Exhibit 1

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-0237 MDL No. 2327
THIS DOCUMENT RELATES TO THE CASES LISTED BELOW	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
Mullins, et al. V. Ethicon, Inc., et al.	2:12-cv-02952
Sprout, et al. V. Ethicon, Inc., et al.	2:12-cv-07924
Iquinto v. Ethicon, Inc., et al.	2:12-cv-09765
Daniel, et al. V. Ethicon, Inc., et al.	2:13-cv-02565
Dillon, et al. V. Ethicon, Inc., et al.	2:13-cv-02919
Webb, et al. V. Ethicon, Inc., et al.	2:13-cv-04517
Martinez v. Ethicon, Inc., et al.	2:13-cv-04730
McIntyre, et al. V. Ethicon, Inc., et al.	2:13-cv-07283
Oxley v. Ethicon, Inc., et al.	2:13-cv-10150
Atkins, et al. V. Ethicon, Inc., et al.	2:13-cv-11022
Garcia v. Ethicon, Inc., et al.	2:13-cv-14355
Lowe v. Ethicon, Inc., et al.	2:13-cv-14718
Dameron, et al. V. Ethicon, Inc., et al.	2:13-cv-14799
Vanbuskirk, et al. V. Ethicon, Inc., et al.	2:13-cv-16183

SEPTEMBER 22, 2015
BRUCE A. ROSENZWEIG, M.D.

CAPTION CONTINUED:

Mullens, et al. V. Ethicon, Inc., et al. 2:13-cv-16564
Shears, et al. V. Ethicon, Inc., et al. 2:13-cv-17012
Javins, et al. V. Ethicon, Inc., et al. 2:13-cv-18479
Barr, et al. V. Ethicon, Inc., et al. 2:13-cv-22606
Lambert v. Ethicon, Inc., et al. 2:13-cv-24393
Cook v. Ethicon, Inc. 2:13-cv-29260
Stevens v. Ethicon, Inc., et al. 2:13-cv-29918
Harmon v. Ethicon, Inc. 2:13-cv-31818
Snodgrass v. Ethicon, Inc., et al. 2:13-cv-31881
Miller v. Ethicon, Inc. 2:13-cv-32627
Matney, et al. V. Ethicon, Inc., et al. 2:14-cv-09195
Jones, et al. V. Ethicon, Inc., et al. 2:14-cv-09517
Humbert v. Ethicon, Inc., et al. 2:14-cv-10640
Gillum, et al. V. Ethicon, Inc., et al. 2:14-cv-12756
Whisner, et al. V. Ethicon, Inc., et al. 2:14-cv-13023
Tomblin v. Ethicon, Inc., et al. 2:14-cv-14664
Schepleng v. Ethicon, Inc., et al. 2:14-cv-16061
Tyler, et al. V. Ethicon, Inc., et al. 2:14-cv-19110
Kelly, et al. V. Ethicon, Inc., et al. 2:14-cv-22079
Lundell v. Ethicon, Inc., et al. 2:14-cv-24911
Cheshire, et al. V. Ethicon, Inc., et al. 2:14-cv-24999
Burgoyne, et al., V. Ethicon, Inc., et al. 2:14-cv-28620
Bennett, et al., V. Ethicon, Inc., et al. 2:14-cv-29624

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SEPTEMBER 22, 2015

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The deposition of BRUCE A. ROSENZWEIG, M.D., called for examination, taken pursuant to the Federal Rules of Civil Procedure of the United States District Courts pertaining to the taking of depositions, taken before JULIANA F. ZAJICEK, CSR No. 84-2604, a Certified Shorthand Reporter of said State of Illinois, at the offices of Wexler Wallace LLP, Suite 3300, 55 West Monroe Street, Chicago, Illinois, on September 22, 2015, at 10:05 a.m.

PRESENT:

APPEARED ON BEHALF OF THE PLAINTIFFS:
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REPORTED BY: JULIANA F. ZAJICEK, C.S.R.
CERTIFICATE NO. 84-2604.

I N D E X

E X H I B I T S

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E X H I B I T S (Continued)

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E X H I B I T S (Continued)

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E X H I B I T S (Continued)

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(WHEREUPON, the witness was duly sworn.)

BRUCE A. ROSENZWEIG, M.D., called as a witness herein, having been first duly sworn, was examined and testified as follows:

EXAMINATION

BY MR. SNELL:

Q. Good morning, Dr. Rosenzweig. How are you doing?

A. Good morning, sir. Just fine. Thank you.

Q. I'm here to take your deposition in the Mullins case which is a multi-plaintiff case currently pending in the Ethicon MDL.

You are aware of that, right, Doctor?

A. Yes.

(WHEREUPON, a certain document was marked Rosenzweig Deposition Exhibit No. 1, for identification, as of 09/22/2015.)

BY MR. SNELL:

Q. And I've handed you Exhibit No. 1 which I will represent to be your Notice of Deposition.

Have you seen this document before, sir?

A. Yes, I have.

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Q. The schedule I attached to it, I asked that you bring various materials and documents to the deposition to the extent you have them.

Did you bring any materials to today's deposition?

A. I have not submitted a bill yet for the work I've done on this case. You guys have an up-to-date copy of my CV. I just supplied a copy of my most recent testimony history. And so there is nothing else on this list that I have.

Q. Do you have a file for the Mullins case?

A. A file?

Q. A collection of all of the literature and the accompanying documents and things like that that you cite to in your Mullins' expert report?

A. Electronically.

Q. Do you happen to have that with you or is it on a thumb drive that I can get?

A. I know you can get a copy of the thumb drive or probably a Dropbox link.

Q. You said you had not billed for your time in the Mullins case yet.

My question is: How many hours have you spent on the Mullins case? And your best estimate is fine.

A. Yes. Approximately 35 to 40 hours. You know, it is difficult to say because, you know, obviously I just gave a TVT retropubic deposition. I've been doing work and keeping up with the literature on other cases. So, I mean, obviously I didn't really need to replow a lot of the literature I've reviewed or depositions that I've reviewed before, so that's why. I mean, a best estimate would be about 35 hours.

Q. Fair enough.

And just remind me, what is your hourly rate for review and things of that nature?

A. 750 an hour for review, $1500 an hour for depositions, and $10,000 a day for trial testimony.

Q. Thank you.

Can you briefly and quickly tell me to what professional societies, if any, do you currently belong to today?

A. None.

Q. I know you and I have discussed your practice in past depositions, and I don't want to rehash a lot of old ground, and I will actually ask you this:

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In connection with today's deposition, can I rely upon your prior sworn testimony you've given to me and other lawyers in the Ethicon litigation?

A. Yes, sir.

Q. Okay. With that being said, it's been a little while since I deposed you and asked you about your stress incontinence work, and I don't want to talk to you about prolapse, because you and I have already talked about that earlier in the summer and I'll respect that.

Currently as you sit here today as a surgeon, what stress incontinence surgeries are you performing or offering to your patients?

A. Yes. It's the same ones we talked about the last time. My primary operation is the Burch procedure. I use pubovaginal slings is what I call my rescue operation. I do periurethral injections for patients. So those would be the core of my surgical procedures for stress urinary incontinence.

Q. Perfect.

You and I have also discussed your practice, you know, what you do generally week to week.

As you currently sit here today, can you

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tell me, has your practice changed significantly?
A. No, sir.
Q. Last Friday I took the deposition of one of the other experts for the Plaintiffs, a Dr. Jerry Blaivas in New York City.
My question is do you know Dr. Blaivas?
A. I know of Dr. Blaivas. I probably met him a couple of times in the past.
Q. Have you ever met him in connection with the litigation or were these meetings where you met him in connection with non-litigation events?
A. Non-litigation events.
Q. Have you read Dr. Blaivas' deposition that he gave to me last Friday?
A. Yes, I have.
Q. When did you receive that deposition?
A. Last weekend.
Q. And I take it Dr. Blaivas' deposition was provided to you by the Plaintiffs, correct?
A. That is correct.
Q. Did you see any misstatements in Dr. Blaivas' testimony or -- strike that.
Did you see any testimony by Dr. Blaivas which you believe was inaccurate?

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MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. Not that I specifically recall.
BY MR. SNELL:
Q. There have been expert reports served by the defense as well in this matter, Drs. Kenton, Toglia and Woods.
Have you seen their expert reports?
A. Not yet.
Q. I'll just say their full names for the record so that you are aware.
Kimberly Kenton, she is a urogynecologist here in Chicago?
A. At Northwestern, yes.
Q. Marc Toglia who is in Philadelphia, he is a urogynecologist, and Michael Woods who is in Iowa, I think.
My question to you is do you know any of those three experts?
A. I know Dr. Kenton.
Q. Okay. Have you ever practiced with her?
A. No.
Q. Have you ever seen Dr. Kenton operate?
A. No.

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Q. Have you ever seen any of Dr. Kenton's patients?
A. There are -- you know, Chicago is not that big of a city, even though, you know, it is the third largest city in the United States, so we all have seen each other's patients from time to time.
Q. As you sit here today, can you think of any TVT patients that Dr. Kenton had who you have seen?
A. Not that I specifically recall.
Q. Can you think of any of Dr. Kenton's patients who have had any type of stress incontinence mesh who you have seen?
A. Not that I specifically recall, but it would not surprise me if I've seen some of her stress incontinence patients, just like it wouldn't surprise me if she has seen some of my stress incontinence patients.
Q. Have you made any referrals to Dr. Kenton for any type of pelvic health condition? Strike that. That's a terrible question. It makes no sense.
Have you made any referrals to Dr. Kenton for her to see one of your patients?
A. Not that I specifically recall.

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Q. I will represent to you that the judge in the Mullins case issued an order by which he identified what will be at issue, namely, design defect of the TVT in that claim. And he provided some language in what the parties should look to in his opinion.
My question to you is: Have you seen the Judge's order on the design defect element and what is to be expected of the parties according to that order?
A. I have not seen that specific order, no.
Q. Changing topics.
What is the average length in centimeters of the vagina of a woman who is of the age for which TVT may be considered as an option to treat her stress incontinence?
A. The average length of the vagina is about 10 centimeters, in a range of about 8 to 10 centimeters.
Q. What, Doctor, in your opinion is the utility, and when I say utility, I mean the usefulness of TVT to the user, like a surgeon like yourself, and to society as a whole in its intended application to treat stress incontinence?
A. What is -- what is the utility?

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Q. Yes, sir. It's usefulness, defined as to the user, like the surgeon or to the public as a whole.
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. It is a surgical treatment for stress urinary incontinence.
BY MR. SNELL:
Q. What, if any, are the useful attributes of the TVT device?
MR. CARTMELL: Object to form.
BY THE WITNESS:
A. Theoretically, it has a shorter operating time, a shorter hospitalization stay, a shorter perioperative recovery. However, the significant risks associated with it outweigh those theoretical benefits.
BY MR. SNELL:
Q. So focusing on the usefulness, you identified shorter operative time. And I'll be fair to you. I heard what you said totally about risk and I'm going to ask you all about risk, but I just want to focus on part one of this decision issue, which is usefulness or utility.

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Shorter operative time, you would agree that the medical literature, including some well respected reviews like Cochrane reviews, do report that with the TVT it does have a shorter operative time compared to other stress incontinence surgeries?
A. Yes, but in a clinically significant sense, a difference between a 20- to 30-minute operation and a 45-minute to an hour operation as far as the risk of being on the operating table, the risk of being under general anesthesia, things such as deep venous thrombosis, you don't see that risk go up until after a two-hour operation. The risk of respiratory compromise postoperatively, things like atelectasis, things like postoperative pneumonias, you don't see a clinically significant utility in that short of an operative time.
Q. And, so, let me ask you this, based on what you just told me, what would be the articles or studies you are relying on for that statement, that there is -- you don't see a clinically significant benefit translating from the shorter operative time with TVT?
A. Well, the shorter operating time and the parameters that we are talking about, and I used, you

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know, deep venous thrombosis. If you look at the gynecologic surgery literature, you start to see an increase in the risk of deep venous thrombosis with a longer operating time above the two-hour range. Once you get up to four hours, you re-dose prophylactic antibiotics.
So, while I agree with you that the literature does show a shorter operating time, when you are in -- the operating time that we are talking about, the clinical utility of that might not be clinically significant.
Q. And what literature or studies are you relying on for that statement that the clinical result might not be significant?
A. That's the general gynecologic surgical literature, my clinical experience and my training.
Q. Are there -- there are no particular studies you are relying on?
A. Not specifically.
Q. You are aware the literature -- strike that.
You are aware that the medical literature in women, clinical studies in women do report a shorter hospital stay with TVT compared to other

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stress incontinent surgeries?
A. Yes.
Q. And you have read the medical literature that also reports that TVT has a shorter perioperative recovery period than an autologous sling or the Burch colposuspension?
A. Yes.
Q. And you've seen that reported in reliable sources like the Cochrane review as well, correct?
A. Yes.
(WHEREUPON, Mr. Paul S. Rosenblatt entered the deposition proceedings.)
BY MR. SNELL:
Q. To you as a surgeon, is it desirable to have a shorter perioperative recovery period?
A. If the long-term risks associated with that shorter operative time and shorter recovery time are similar, if you're not giving up long-term adverse events that are significant to the patient, that have a significant impact on the patient, such as the need to return to the operating room to treat a long-term adverse event, if those are similar, than a shorter operating time and a shorter recovery would be more of an economic advantage. You I know, it does cost more

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money to be in the operating room, it does cost more money to be in the hospital. Getting back to a week or so earlier to productivity is -- you know, would have an economic basis, but that's got to be looked at in comparison to long-term adverse events and significant adverse events that will impact a woman's life.

Q. So focusing on the utility, you've identified that a shorter operative time does have an economic benefit?

A. That is correct.

Q. And a shorter postoperative recovery period does have an economic benefit?

A. That is correct.

Q. And you gave an example that women may return to their normal activities, like their job, sooner, correct?

A. That is correct.

Q. And so that would be a benefit to the potential women who would receive the device, correct?

A. If that is not offset by significant long-term adverse events. So, such as if someone has to return to the operating room to treat a long-term adverse event, then they incur that economic

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disadvantage and then, therefore, you know, the economic advantage of the initial surgery would be washed out by the economic disadvantage of future surgery.

Q. I hear you on risk, but just so we're clear, the shorter postoperative recovery realized by a patient who receives TVT would be an economic benefit to that patient?

A. If you are just looking at it in a vacuum and not looking at the future long-term risk associated with it, then that vacuum would be of an economic advantage with shorter operating time, shorter hospitalization.

Q. To you as the user or intended user -- let me back up.

So the intended user of a TVT, the one who wields the TVT is a surgeon, correct?

A. That is correct.

Q. To you as an intended user of TVT, the surgeon, what from your perspective is the benefit or desirability of your patient having a shorter postoperative recovery period?

MR. CARTMELL: Object to the form.

BY THE WITNESS:

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A. Again, the shorter postoperative recovery, the quicker someone can get back to their daily activities of life, take care of their family, get back to work. Is that clinically significant if you are talking about a difference of one to two weeks, I'm not sure that that truly becomes a clinical utility, but it is a theoretical advantage.

BY MR. SNELL:

Q. Is there a benefit to you as the intended user of TVT when your patient has a shorter hospital stay?

A. Again, we are -- you know, the theoretical advantages of that would be, again, economic as we talked about. There theoretically would be a -- less exposure to nosocomial or hospital-acquired infections. However, those are significantly reduced in the kind of environment that our gynecologic patients are on versus someone that's on an internal medicine floor.

Q. Anything else you can think of with regard to the benefit for a shorter hospital stay?

A. Those would be the theoretical advantages.

Q. You've read the early papers from the 1980s and 1990s by Dr. Petros and Dr. Ulmsten?

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A. Yes.

Q. So you've seen that they set about with certain goals in mind, namely to have an ambulatory-type stress incontinence procedure that would be minimally invasive and then they worked around those goals?

MR. CARTMELL: Object to the form.

BY THE WITNESS:

A. If you have, you know, a specific paper that you want to talk about that sets out those -- those goals, it would be important to look at to acknowledge that. What were the goals that they have set out?

BY MR. SNELL:

Q. I don't have a specific paper. I'm just saying, are you aware that they had goals that they had set out for the stress incontinence procedure that they worked on developing?

MR. CARTMELL: Object to the form.

BY MR. SNELL:

Q. In your general reading of the literature and your knowledge in the field over the past 30 years?

A. Right. I would say that they definitely

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had goals, No. 1, to treat stress urinary incontinence. We know from Dr. Ulmsten's early reports and also correspondence that Dr. Ulmsten had that he considered doing the procedure under local anesthesia. Paramount for safety and efficacy reasons, we know that one of his early collaborators, Dr. Nilsson, stated that the success rate goes down when it's done under general anesthesia. So to say that he was developing a procedure to be done under a local anesthesia is the type of procedure that he developed and the -- that he significantly recommended unless there were extenuating circumstances that this procedure be done under local anesthesia.

Q. You are aware that one of the goals of the development of what became TVT by Drs. Petros and Ulmsten -- let me back up.

Have you ever met Dr. Petros?

A. No, I have not.

Q. He is from Australia?

A. I would -- if that's where he is from. I don't know where he is from.

Q. Okay. Fair enough.

You are aware that one of the goals that Drs. Petros and Ulmsten had was to develop what they

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termed as an ambulatory stress urinary incontinence procedure?

MR. CARTMELL: Object to the form.

BY THE WITNESS:

A. Again, I know that from Dr. Ulmsten's papers and correspondence that he has had with Ethicon early in the late '90s that the procedure was done under local anesthesia and that it should be done under local anesthesia and that unless there is extenuating circumstances to do it under general anesthesia, he found that local anesthesia was for safety and efficacy reasons. Now, whether his ultimate goal was to do this under an ambulatory setting, I don't recall seeing that written in papers or in other correspondence documents that I've seen.

BY MR. SNELL:

Q. Okay. So let's just make sure I get a clean answer. I think you answered my question, but at the very, very tail end.

As with regard to Dr. Petros and Ulmsten's goal of having an ambulatory stress urinary incontinence procedure, you do not recall that being discussed in their publications and statements, fair?

A. I don't specifically recall that

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statement, no.

Q. Do you recognize that Dr. Ulmsten and Dr. Petros had a goal to develop a minimally invasive stress urinary incontinence procedure for women?

A. Well, in theory that is how it's described, but taking a trochar, which is a spear, if you will, that is approximately 6 millimeters in diameter and poking it blindly through the retropubic space, while the incisions that are made are small, there is still an invasiveness to the procedure.

Q. You and I can agree that every stress urinary incontinence surgery has some invasiveness, right?

A. That is correct.

Q. Every incision is invasive, correct?

A. That is correct.

Q. However, the TVT is less invasive compared to an open Burch colposuspension, correct?

MR. CARTMELL: Object to the form.

BY THE WITNESS:

A. I'll agree with you that the incisions made on the abdominal wall are smaller. You have two 1-centimeter incisions which equal 2 centimeters, where in a Burch procedure you can do this in a 4- to

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6-centimeter incision. So your incisions in the abdominal are greater. However, you don't have a vaginal incision which with the TVT is approximately 1.5 centimeters long. So if you add up all of the incisions together, they are fairly equivalent. But I agreed with you that the abdominal incisions are smaller.

Q. How big did you say the abdominal incisions were for TVT?

A. 1 centimeter.

Q. Each?

A. Yes.

Q. And how long did you say the incision above the rectus fascia was for an open Burch colposuspension?

A. The skin incision?

Q. The incision, how long is the incision?

A. The skin incision, 4 to 6 centimeters.

Q. How much --

A. Now, depending on if you are doing a concomitant hysterectomy, you might need to make a bigger incision, or if you are doing a concomitant abdominal colposacropexy or some other procedure, but if we are just talking -- and obviously if you are

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doing those things with TVT, you couldn't do those under local.
Q. Burch is never done under local anesthesia, correct?
A. Oh, it's been done under local.
Q. Have you ever done it under local?
A. I have not personally done it under local, but it has been described in the literature that it can be done under local.
Q. Is the Burch recommended to be done locally?
A. There is no specific recommendation to do it under local or specific recommendation not to do it under local.
Q. When you do the Burch, do you do it under regional block or general anesthesia or is it dependent upon what other concomitant procedures you are going to be doing at the same time, if any?
A. There are a variety of different decisions that can be made about what type of anesthesia you use.
Q. If I can recall correctly, you don't harvest fascia from the fascia lata, a woman's thigh, in your Burch procedure?

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A. You do not need to harvest fascia for a Burch procedure.
Q. I just realized that when I asked you that question. Okay.
A. Did you get a good night's sleep last night, Burt?
Q. I did, actually surprisingly. I think I know a little bit about this stuff. That was an off-the-wall question. When it came out, I thought, there's something really wrong there. I can't put my finger on it.
A. Move to strike as non-responsive.
Q. No, I did get a good night's sleep, for sure.
To you as a surgeon, what utility or usefulness is there in having a procedure that is less than -- less invasive at the time of surgery than other alternatives?
A. You can decrease perioperative morbidity theoretically.
Q. When you say "perioperative morbidity", do you mean morbidity while the patient is in the hospital or are you focusing on during the actual procedure itself or is it more than that?

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A. Well, intraoperative morbidity would be events that happened while the surgical procedure is going on. Perioperative morbidity is the events that happened after the surgery is done but during the normal 4- to 6-week recovery time.
Q. Before TVT came to the market -- and let's just say we'll talk about the worldwide market, but certainly I'm interested in the United States, so with that caveat.
Before TVT came to the market, was there a desirability to have a minimally invasive stress urinary incontinence option to treat women with?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. Well, there were procedures, such as the needle procedure, the Stamey, the Raz, the four-corner Raz procedure, the Gittes procedure, that were -- the Pereyra procedure, that were variations on the same theme that where a thin needle was placed through the retropubic space which could be done under local anesthesia. The Gittes operation is one where you could significantly do that under local anesthesia, but all of them could be done under local anesthesia. So, I think that was not a significantly unique

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concept that was being discussed in the incontinence market.
BY MR. SNELL:
Q. You do acknowledge, though, that there was a desire coming from surgeons as well as patients who would undergo the surgery that there be a more minimally invasive option --
MR. CARTMELL: Object to the form.
BY MR. SNELL:
Q. -- prior to TVT coming to the market, correct?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. There were the same options. I mean, you had needle procedures that could be done through a small 1 centimeter or less incision above the pubic bone and a small incision in the vagina.
BY MR. SNELL:
Q. And the reason why the needle procedures were in place and as options was because of the desire towards minimally invasive options to treat stress urinary incontinence, correct?
MR. CARTMELL: Object to the form.
BY THE WITNESS:

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A. It was one of the options that were available.
BY MR. SNELL:
Q. You would agree that, as you've told me, the benefit to these needle suspension procedures was that they were minimally invasive compared to the other stress urinary incontinence surgeries, correct?
A. I agreed with you that there was a smaller incision made on the abdominal wall and that you -- however the invasiveness of passing a needle blindly through the retropubic space was still present. What I did agree with you was that these could be done under local.
Q. You are critical of the TVT in that you say there is a blind passage of the trochar through the retropubic space, correct?
A. Passing a 5- to 6-millimeter in diameter trochar through the retropubic space has been associated with intraoperative injuries, such as bladder injury, urethral injury and bowel injury.
Q. Back to my question.
You are critical of the TVT in that it has what you term blind passages through the retropubic space with the trochar, correct?

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A. The size trochar going blindly through the retropubic space does increase the intraoperative risk.
Q. What studies are you relying upon for that statement that the size of the trochar going through the retropubic space increases the risk of complications?
A. Well, when you look at the early literature that showed the reports of bowel injuries and the deaths associated with bowel injuries, when you look at the retropubic literature compared to the other midurethral slings and a quoted bladder perforation rate with retropubic slings is in the 5 to 15 percent where it is less than 5 percent for the non-retropubic midurethral slings, that's the literature I'm discussing.
Q. My question is specific to this:
What literature, if any, clinical studies in women, are you relying on for the statement that the actual size of the trochar going through the retropubic space increases the risk of complications?
MR. CARTMELL: Object to the form, asked and answered.
BY THE WITNESS:

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A. The studies that I'm relying on are the ones that I've described for you.
BY MR. SNELL:
Q. Okay. I don't think we are communicating. All right.
So, trochar can be different sizes, correct?
A. That is correct.
Q. Have you seen any randomized controlled trials or other comparative studies that looked at and that showed that the size of the trochar at 6 millimeters as opposed to 4 millimeters or some other size, that that size element affected the complication rate? Do you understand what I'm asking? I'm really focused on just size of the trochar, 6 and 4, you know.
A. That did a prospective randomized trial on two different trochar sizes and looked at the specific bladder perforation rate?
Q. Okay. So now at least we are on the -- we are running down the same track. Let me reformulate the question.
A. Right.
Q. Are you aware -- and I'm going to ask you

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about comparative studies.
Are you aware of any comparative studies that showed that having a larger size trochar for the TVT led to an increased rate of complications that was statistically significantly higher than a smaller size trochar placed in the same manner?
MR. CARTMELL: Just so I'm clear, is the question has that been studied -- has that study been done or has he seen that study?
MR. SNELL: Is he aware of that, has it been done, has he seen that data?
BY THE WITNESS:
A. I am not aware of that data.
BY MR. SNELL:
Q. You mentioned that with -- strike that.
You mentioned compared -- strike that.
You mentioned that with the transobturator route of placement of the TVT mesh that there is a lower rate of bladder perforation as compared to the TVT retropubic, correct?
A. That is correct.
Q. And you're also aware that Ethicon makes that design -- strike that.
You are aware that Ethicon makes that

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TVT-O designed trochar -- strike that.
You are aware that Ethicon makes the transobturator designed TVT-O passage available to surgeons, correct?
A. That is correct.
Q. And you yourself have testified that there are risks associated specifically with that transobturator passage, correct?
A. That is correct.
Q. And that's reflected in the medical literature, like the Cochrane reviews and other systematic reviews and meta-analyses that you view as reliable, correct?
A. They are on my reliance list, yes.
Q. But you viewed them as reliable, correct?
A. That is correct.
Q. The needle procedures that you identified earlier, like the Stamey, the Gittes, the Raz, those procedures are not recommended by any of the professional societies here in the United States as a first line surgical option to treat stress urinary incontinence, correct?
A. That is correct.
Q. When is the last time you performed one of

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those needle procedures for stress urinary incontinence treatment, if you've ever done one?
A. Well, I've done them before, yes.
Q. I didn't remember we had ever discussed that, but, I mean, that's going way back, so let's -- when was the last time you've performed one of these needle suspension procedures for the treatment of stress urinary incontinence, Doctor?
A. Probably in the late '90s.
Q. And you have seen reliable well-done systematic reviews and meta-analyses that report that the efficacy with the needle suspension procedures, such as the Stamey, the Gittes and the Pereyra, is inferior to other stress urinary incontinence surgeries, like the Burch and pubovaginal sling and the midurethral sling, the full-length midurethral sling, correct?
A. I'm not sure whether there are meta-analysis, but there are opinions that have been put forth that the success rate is lower for the needle procedures compared to the Burch, pubovaginal sling and midurethral sling.
Q. Have you reviewed any of the comparative randomized control trials, if any, that look at and

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compare the needle suspension procedures we've been discussing for the treatment of stress incontinence to the Burch, the autologous sling or the full-length midurethral slings?
A. There might be some procedure -- or might be some literature in -- that addresses some comparative studies. However, I would agree with you -- and remember we got talking about needle procedures when you were asking me about procedures that were done in the '80s and '90s, and so I was describing that. I would agree with you that most if not -- most urogynecologists do not use needle procedures as first-line therapy unless there is a significant indication for it.
Q. As you sit here today, can you think of any significant indication for one of these needle procedures over and above the use of an alternative like the Burch, a pubovaginal autologous sling or a full-length midurethral sling?
A. Well, I think there are still some pretty good data on the four-corner Raz procedure which is, quote/unquote, a vaginal pubovaginal sling, but the Pereyra, the Gittes, the Stamey, I think that those are -- unless under rare circumstances and rare

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instances would not be considered first-line therapy.
Q. Have you done a systematic review of the medical literature reporting on these needle suspension procedures?
A. I probably did a systematic review of that literature years ago when I was using those procedures, but I must admit I probably have not looked at that literature in -- that specific literature. You know, obviously I've reviewed the overwhelming majority of midurethral sling literature and Burch literature as we've discussed on several different occasions, but I would admit I have not looked at the needle procedure literature in a while.
Q. You mentioned that you -- was it your recollection or just your kind of general impression that of the needle suspension procedures, the four-corner Raz procedure had the better data?
A. Yes, and it's more of a vaginal pubovaginal sling is what Raz described.
Q. Has the four-corner Raz procedure been studied in a randomized control trial to the pubovaginal autologous sling, the Burch colposuspension or the full-length midurethral sling like TVT that you are aware of?

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A. Not that I'm aware of.
Q. Is it desirable to you as a surgeon to have surgical options that have actually been studied in randomized control trials?
A. Randomized control trials would be the highest level of evidence in the study literature, if you will. It helps in making evidence-based medicine decisions. And, so, therefore, I would -- I use evidence-based medicine in making my decision-making for patient management and, therefore, would use randomized control trials in making decisions.
Q. In the 1990s, are you aware if there were any systematic reviews and meta-analyses done looking at randomized control trials that assessed the different surgeries to treat stress urinary incontinence?
A. Specifically in the mid-'90s?
Q. Any time in the 1990s.
A. Whether there were -- now, remember, when you do a systematic review, you are looking at mostly randomized control trials. You -- some systematic reviews add in other well-done cohort studies or comparative studies, but for the vast majority of systematic reviews, randomized control trials are --

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are used and also assessed for their quality.
Sitting here today, I quite frankly do not recall if there were specific meta-analyses and systematic reviews that were done. I do know the current meta-analyses and systematic reviews and Cochrane reviews that, you know, we might touch on today.
Q. Fair enough.
You were doing the Burch colposuspension, as I recall, and you've told me this, and I want to make sure I'm correct. Withdraw.
You were doing the Burch colposuspension throughout the 1990s, correct?
A. That is correct.
Q. Were there any randomized control trials that you are aware of that were conducted on the Burch colposuspension in the 1990s that informed your practice?
A. Well, randomized control trials would be randomizing to two different arms. And while there might have been some studies that looked at a comparison between Burches and pubovaginal slings or Burches and needle procedures, specific randomized control trials in that era I am not aware of right

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now.
Q. You've seen, I take it, the statement in the literature by certain "experts" that there have been over 100 surgeries, different procedures to treat stress urinary incontinence.
Are you familiar with that?
A. I've seen that, numbers like that thrown around, yes.
Q. Is that something you learned during your medical school or your gynecologic residency training?
A. That statement that there were over 100 incontinence operations?
Q. Yes, Doctor.
A. That specific statement, no.
Q. Do you have an opinion as to how many different stress urinary incontinence surgery options there have been described?
A. There have been a number, but they are all pretty much variations on a similar theme. I mean, there were the retropubic operation, there were the pubovaginal sling operations, there were the needle procedure operation, so that there was a -- while people might describe a different way of doing a specific part of a specific operation, there were

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pretty much the same categories that we have today.
Q. And when you say "retropubic", you are including in that the lineage of the MMK and the Burch, correct?
A. Well, the MMK, the Burch, the Tanagho modification of the Burch. Again, a new procedure might be a modification of a procedure and, therefore, you know, might be considered a "new" procedure where it is really just a variation on the same theme.
Q. In all of these -- so the retropubic procedures, the pubovaginal sling procedures and the needle procedures, are those like the top-line branches for doing stress urinary incontinence procedures?
A. We are talking about in that era?
Q. Or in the 1990s, before TVT came about.
A. Those would be the major categories that operations would fall under. There was the Kelly-Kennedy plication with an anterior colporrhaphy. That would be an operation that, you know, was known to have a fairly low success rate and would be of a utility in certain situations, such as doing a Lefort colpocleisis. In an older woman you do a Kelly-Kennedy plication to try to prevent that from

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developing a post-operative stress incontinence.
Q. As I understand it, the Kelly plication is not recommended as a first-line surgical option to treat stress urinary incontinence by any of the professional societies here in the United States who puts out guidelines and analyses regarding stress incontinence procedures, is that correct?
A. I would agree with you there might be certain situations, the one that I just described for you, where it would be a -- a procedure of utility, but I would not recommend it as first-line therapy.
Q. Is there any category of stress urinary incontinence surgery that avoids the retropubic space?
A. Is there any category?
Q. Yes. You told me there were different categories, retropubic, pubovaginal sling, the needle procedures.
My question is: Do any of those categories of procedures avoid the retropubic space?
A. No.
Q. Is it necessary to enter the retropubic space in order to treat stress urinary incontinence?
A. And we are not dealing with transobturator slings which have been suggested to not enter the

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retropubic space, but if you actually do dissect into the retropubic space, you can find transobturator slings in the retropubic space, so if we are just -- we are going to keep that out of our discussion?
Q. Well, let me just make sure I understand that. Or let me just ask you a clean question, a broader question then.
In your opinion is there any stress urinary incontinence surgery that avoids the retropubic space?
A. Again, beside the opinion that -- and possibly some anatomic dissections that would suggest that the transobturator slings avoid the retropubic space, I've dissected them out of the retropubic space. So those might have migrated into the retropubic space and that was what was causing their -- the patient's complications. But the ones that we are talking about today, the urethropexies, the midurethral slings, retropubic and the needle procedures all enter the retropubic space.
Q. For the needle suspension procedures that we have been discussing to treat stress urinary incontinence, there is a blind passage of surgical instruments during those procedures, correct?

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A. That is correct.
Q. During the autologous pubovaginal -- strike that.
During the autologous pubovaginal sling placement, there is the blind use of surgical instruments in that surgery as well, correct?
A. Not the way I perform it.
Q. So just so I'm clear, the way you performed the autologous pubovaginal sling, there is no part of that surgery where there is a blind use of a surgical instrument?
A. That is correct.
Q. Describe how you do that pubovaginal sling where you avoid the --
A. So we've had this discussion, but I will describe it for you.
Q. Very briefly just so I understand.
A. You make similar to a Burch incision, you harvest the rectus fascia, you bring it down on each side of the urethra, and then you bring it under -- one side underneath the urethra and you attach the two ends together. So it is done through a retropubic incision.
Now, you can do a pubovaginal sling with

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instruments that are blindly passed through the retropubic space.
Q. You saw in Dr. Blaivas' testimony he testified that when he does the autologous pubovaginal sling, part of his placement and use of the needles is in a blind fashion, correct?
A. That is correct. You can use needles, you can use other less -- or another instrument to pass the rectus fascia.
Q. You can use less invasive instruments than the needles to pass the rectus fascia, correct?
A. That is correct.
Q. But Dr. Blaivas for whatever reason chooses to use the more invasive needles, correct?
A. What he described in his deposition is what he described in his deposition.
Q. And that's the more invasive needles compared to the tools you use, correct?
A. Again, I don't use needles or blunt instruments except to create a tunnel underneath the urethra at the bladder neck.
Q. You would agree, and I think you will, that the needles Dr. Blaivas uses are more invasive, correct?

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A. And I think now we are agreeing that there is an invasiveness, even if it's a minimally invasive, that passing a needle is an invasive procedure, and I will agree with that.
Q. During your autologous pubovaginal sling, are you tying it up top or are you tying it through a vaginal incision?
A. You can make a vaginal incision to be able to connect the two ends of the pubovaginal sling or you can harvest a full length of pubovaginal sling or rectus fascia. What I do is I take two ends and bring them together on the side of the urethra so I don't have a suture line underneath the urethra. But it is all done retropubically, so I don't make an incision in the vagina.
Q. So you do a suprapubic incision and you take the sling and you position it under visualization while you are looking down into the space of Retzius, correct?
A. That is correct.
Q. And is it off to the left side or the right side where you connect the strip of fascia?
A. Being left-handed, I connect things on the left side.

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MR. SNELL: Okay. Let's take a break.
(WHEREUPON, a recess was had from 11:05 to 11:17 a.m.)
BY MR. SNELL:
Q. So before we took our break we were discussing various stress urinary incontinence procedures, and you had told me that the older needle suspension procedures and the autologous fascial sling, there can be passage of needles through the retropubic space, correct?
A. That is correct.
Q. And that occurred before TVT, correct?
A. Yes.
Q. And is it correct that even after TVT was introduced that surgeons using those older needle suspension procedures and the autologous slings if they so chose still use blind passage of instruments through the retropubic space?
A. Well, there are still a number of surgeons and a growing number of surgeons that are using the alternative surgeries to the midurethral sling. They look at the risk/benefit analysis of midurethral slings and say that the long-term risk associated with midurethral slings outweigh the benefits and have gone

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back to pubovaginal slings or the Burch procedure. I would agree with you that the needle procedures in and of themselves are not used very much anymore, if at all.
Q. I think you mistook my question, so let me see if I can make it -- because I'm not really interested in percentages or anything like that. I guess I should have asked a more simple question.
Surgeons who chose to do the pubovaginal slings and these needle suspension procedures after TVT even came to the market still would employ the blind passage of the instruments through the retropubic space?
A. In doing those procedures?
Q. Yes, sir.
A. Yes.
Q. So then you would agree that it was consistent with the state of the art when TVT was designed to have surgical instruments pass through the retropubic space?
A. The retropubic space was used to pass instruments to accomplish stress incontinence procedures.
Q. Is that a yes?

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A. The -- the state of the art?
Q. Yes, it was consistent with the state of the art when TVT was designed to have surgical instruments pass through the retropubic space?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. Yes, instruments are passed through the retropubic space, yes.
BY MR. SNELL:
Q. It was also consistent with the state of the art when TVT was designed to have surgical instruments pass through the retropubic space with a portion of that passage being blind, correct?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. Procedures are still accomplished with a portion of the procedure or certain procedures done with a blind passage.
BY MR. SNELL:
Q. Is that a yes?
A. Yes.
Q. It was consistent with the state of the art when TVT was designed to have vaginal incisions used to carry out the stress incontinent surgery,

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correct?
A. Yes.
Q. It was consistent with the state of the art when TVT was designed to have multiple incisions utilized to carry out the stress incontinent surgery, correct?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. Yes.
BY MR. SNELL:
Q. Earlier you mentioned bladder perforation in that risk with the retropubic passage.
Do you recall that?
A. Yes.
Q. Now, I know you've read the Cochrane review by Ogah from 2008. Strike that.
I know you read the Cochrane review by Ogah from 2009 and it was updated and published in 2011, correct?
A. That is correct.
Q. And you recall that in that Cochrane review they looked at were there any significant differences in the comparative studies for doing a bottom-up passage, like a TVT retropubic, compared to

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a top-down passage, correct?
A. Correct, and if you want to get into a discussion any more than that, I'm going to need to see it.
Q. Well, let me ask you this:
I take it you don't based on the literature have an opinion that TVT retropubic has a higher rate of bladder perforation than other retropubic midurethral full-length slings?
A. I don't have an opinion about that that it has a higher rate of bladder perforation than other retropubic midurethral slings.
Q. Full-length midurethral slings, correct?
A. And we're specifically talking about the Ogah 2011 Cochrane review?
Q. No. So let's back up.
A. Okay.
Q. So I know you've told me in that your opinion the retropubic passage has a risk of bladder perforation that's higher than a transobturator passage, correct?
A. That is correct.
Q. So let's set that to the side because we've already talked about transobturator.

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You would agree that the overall data do not show that for retropubic midurethral slings that the rate of bladder perforation with TVT is statistically significant, not only higher than other retropubic full-length midurethral slings?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. Done bottom up or top down?
BY MR. SNELL:
Q. Either way.
A. I -- in the Ogah Cochrane analysis, that review does discuss differences between the risk of bladder perforation, and if we want to talk about that specifically, we can, you know, look at the paper so I can go to the part on that paper where it says and quote the exact number specifically. There -- from my recall, and we are not making this a guessing game or a memory test, to be able to speak specifically about what the numbers in the Ogah study show, I think it would be helpful to have that study in front of me.
Q. I guess my question, though, is broader than just what Ogah did, although I know you've read and relied on Ogah.
My question was: You don't have an

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opinion that there is a higher bladder perforation rate with the TVT retropubic device as compared to other retropubic midurethral full-length slings, correct?
A. I don't cite that as an opinion in my report.
Q. Fair enough.
MR. SNELL: Can you mark that.
(WHEREUPON, a certain document was marked Rosenzweig Deposition Exhibit No. 2, for identification, as of 09/22/2015.)
BY MR. SNELL:
Q. Doctor, I've handed you Exhibit No. 2 which is the Ogah short Cochrane review from 2011. This is one of the papers you read?
A. That is correct.
Q. This is one of the studies you rely on for your opinions, correct?
A. That is correct.
Q. In this Cochrane review they state, a retropubic bottom-to-top route was more effective than the top-to-bottom route?
A. Yes.

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Q. And the bottom-to-top route would be like TVT, correct?
A. That is correct.
Q. Top-to-bottom would being SPARC and other variants?
A. Well, there is a top-to-bottom application of the TVT retropubic, but specifically, particularly on page 287 --
Q. Correct.
A. -- they compare retropubic bottom-to-top approach TVT versus retropubic top-to-bottom approach SPARC. So they specifically looked at those two parameters.
And your next statement is going to be adverse effects. The bottom-to-top approach reported fewer adverse events, such as bladder perforation, vaginal erosion, voiding dysfunction and tape erosion than the top-to-bottom approach.
Q. And you would agree that the retropubic approach utilized by the design of TVT does result in more efficacy than a top-to-bottom approach utilized by the design of a product like SPARC?
A. Well, that success rate might be explained by not just the approach that's used but differences

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in the mesh specifically, such as pore size, weight of the sling, and other parameters. So it's a little bit difficult to just say that it is the bottom-up versus top-down approach that is associated with an increase in efficacy or the decrease in the adverse events that they describe.
Q. Have you formulated an opinion as to whether it is the bottom-up design approach of the TVT retropubic that leads it to have better efficacy than the top-to-bottom design of the SPARC?
A. Specifically the approach?
Q. Yes, sir.
A. No.
Q. Do you know why the TVT bottom-to-top approach had a lower rate of voiding dysfunction, bladder perforation and tape erosions than the top-to-bottom SPARC design?
MR. CARTMELL: I apologize. Would you please restate that question.
(WHEREUPON, the record was read by the reporter as requested.)
BY THE WITNESS:
A. Specifically comparing two different mesh products that would be a very long discussion about

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the reasons why there would be a difference in efficacy and complication rates.
BY MR. SNELL:
Q. Well, I just want to focus on those three complications.
Why does TVT have a lower rate of bladder perforation, voiding dysfunction and tape erosions than the top-to-bottom design employed by SPARC?
A. And, again, that is a long discussion about the differences between the tape and the approach.
Q. What is it?
A. What is it?
Q. What is the answer to my question?
A. Why is there a higher efficacy and a lower complication rate?
Q. No, no, no. You are not focusing on my question, because I've already set efficacy to the side.
A. Okay.
Q. And I'm not asking about safety altogether. I'm asking these parameters --
A. Right.
Q. -- in the Cochrane review.

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In the Cochrane review why does the TVT with its bottom-up design lead to less voiding dysfunction, bladder perforations and tape erosions than the top-to-bottom design of the SPARC?
MR. CARTMELL: Object to form to the extent that it calls for speculation, lacks foundation and is based on data in studies that he hasn't been provided. I also, you know, just want the record to be clear, I don't think he has offered an opinion in this case, a comparative opinion between the SPARC and the TVT. In other words, he has offered an opinion that the TVT is defective, but you are asking him questions about the SPARC product and reasons why the SPARC product might be defective. And I don't think that's at issue in this case. So I think it is an improper question.
BY MR. SNELL:
Q. You can answer. I'm asking about pertinent complications relative to the TVT. That's my position, so.
A. Yes.
Q. So do you need me to reask the question or do you have it in your mind?
A. I don't think that it is related to the bottom-up versus top-down design approach.

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Q. What design attribute of the TVT, then, leads it to have less tape erosions than the SPARC?
MR. CARTMELL: Same objections.
You are talking about just in these studies or the Ogah study?
MR. SNELL: Yes, as reported in the Ogah Cochrane review.
BY THE WITNESS:
A. What is it about the specific design of the TVT --
BY MR. SNELL:
Q. Yes, what is it about --
A. -- versus the specific design of the SPARC?
Q. Yes.
What is it about the design of the TVT that leads it to have a lower rate of vaginal erosion than the SPARC as reported in the Ogah study?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. Well, the Ogah study doesn't allow me with the information that they have in reviewing four papers to discuss the differences in design that would account for the differences in the complications that

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were described.
BY MR. SNELL:
Q. Now, you earlier told me that you do not believe, though, that it is due to the bottom-up design approach of the TVT as to why those three complications, bladder perforation, voiding dysfunction, vaginal erosions, were lower with TVT compared to SPARC, correct?
A. That specifically, no.
Q. And so what was the methodology by which you made that distinction?
A. The methodology would be reviewing the literature, looking at the way that the studies -- individual studies, the Kim study, the Lim study and the Lord study were designed, looking at the methodology that was used, looking at the sample size to determine whether or not the bottom-up approach versus the top-down approach increased the risk of those specific complications.
Q. So you think there is enough data and methodology in those studies that allows you to opine that the difference seen as reported in Ogah is not because of the route, bottom-to-top versus top-to-bottom?

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MR. CARTMELL: Just let me make it clear for the record. You are asking him to compare the SPARC to the TVT. He is not offering an opinion in this case that the SPARC is safer than the TVT or less safe than the TVT. And his opinions are -- in this case are about the TVT mesh, the trochars, the approach, the procedure. So you are asking methodology questions related to a topic that's not -- to the SPARC. And I just don't think that's relevant here.
MR. SNELL: I heard you the first time, Tom.
MR. CARTMELL: I want the record to be very clear because --
MR. SNELL: It is.
MR. CARTMELL: -- because you're asking methodology questions like you're -- there is some opinion that you are going to move to strike from a Daubert standpoint. But he hasn't been asked to compare the SPARC to the TVT.
MR. SNELL: My position is these are data reporting on complications with the retropubic TVT and this data is certainly relevant. This is the study he cited to, we've discussed before in other contexts. So that's why I'm asking him questions about it.
BY MR. SNELL:

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Q. I just want to make sure I understand where you are coming from.
Do you believe there is enough description data and methodology that you can reliably say that the differences seen in those three adverse effects, of voiding dysfunction, bladder perforation and vaginal erosion, that TVT had the lower rates of those compared to SPARC and that's not due to the bottom up versus top-down approach?
MR. CARTMELL: Same objections.
BY THE WITNESS:
A. Specifically looking at the papers that are quoted in the Ogah analysis?
BY MR. SNELL:
Q. However you would do it. I'm just asking you.
MR. CARTMELL: Object to the form. Also adding it lacks foundation. I'm not sure if you are asking him just based on this paper or his view of all of the literature.
MR. SNELL: No. I'm asking about Ogah.
MR. CARTMELL: Ogah only.
BY THE WITNESS:
A. Right, from the information that is in the

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Ogah Cochrane review, there is -- they are reporting on what they -- what the study showed and what was the difference in outcomes between the retropubic TVT bottom up and the top down. Having reviewed the individual papers, those report information. Now, you're asking me to go beyond what's in those papers, because if you want to pull out each of the individual papers to see if they opined why there was a difference in these complications, then we can look at each individual one.

Q. No, I don't -- I don't think that that's responsive. I'm going to move to strike.

I'm going to make it as simple as I can. Why does TVT have significantly less voiding dysfunction than SPARC as reported in the Ogah Cochrane review?

MR. CARTMELL: Same objections.

BY THE WITNESS:

A. There is no conclusion in the Ogah Cochrane review of why there is less erosion, why there is less voiding dysfunction, and why is there a higher efficacy.

BY MR. SNELL:

Q. Based on your review of those underlying

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studies and the Ogah review, are you able to tell me why TVT had a lower rate of vaginal erosion than SPARC?

A. Specifically based on the Ogah review and reviewing those studies, a -- the reason for the difference specifically in those complications -- and it would be more important for me to have each one of those in my hand to make that final statement, but from what I recall, they do not opine as to why there is a difference between those complications.

Q. But my question is: Do you know why TVT had less vaginal erosions than SPARC?

MR. CARTMELL: Just based on his review of Ogah?

BY MR. SNELL:

Q. Based on all of the work you've ever done and your experience and your knowledge and everything that you bring to the table that you are relying on as an expert?

MR. CARTMELL: Okay. I also want to make it clear because Dr. Rosenzweig has also looked at confidential internal documents from AMS and I'm not sure he is in -- I'm not sure he is allowed to in this deposition talk about any of the opinions he has about the SPARC that are confidential in nature in that

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litigation.

So to the extent you might be, you know, violating some protective order or -- I don't think you should talk about specifically that work related to your review of the SPARC case.

BY THE WITNESS:

A. I don't think I can answer that question without violating protective orders.

BY MR. SNELL:

Q. Which protective orders are you referencing?

A. In AMS.

Q. Well, have you ever opined that SPARC has a higher rate of vaginal erosion than TVT?

A. Again, based on the protective orders that I have signed, I don't think I can answer that question.

Q. You have not opined in a deposition or in a court of law that SPARC has a higher rate of erosion than TVT?

A. Not in a deposition or in a court of law.

Q. Have you written a report where you have stated that SPARC has a higher rate of mesh exposure -- strike that.

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Have you written in a report that SPARC has a higher rate of vaginal erosion than TVT?

A. If I recall, I have quoted the Lim paper and the other papers that are quoted in the Ogah review.

Q. For what purpose did you quote those?

A. Comparative purposes, just like what the Ogah review found.

Q. What specific comparative purposes did you site those materials for?

A. As the Ogah review says, that there is a higher rate of vaginal erosions, voiding dysfunction, and tape erosions associated with the SPARC compared to the TVT.

Q. Why did you find it important to cite that part of the Ogah Cochrane review?

MR. CARTMELL: No. I think he is talking about citing the actual studies, not the -- am I wrong?

BY THE WITNESS:

A. No, citing the actual studies.

BY MR. SNELL:

Q. So why was it important that you cite those actual studies?

A. Without getting into details about what's

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in the reports, as those are still active cases, I don't know if it's appropriate for me to discuss that.
Q. These are expert reports you have in other litigation, in the AMS litigation?
A. That is correct.
Q. Do you have copies of those reports?
A. Not with me.
Q. Have you produced those reports that have been disclosed by Dr. Rosenzweig in other mesh litigations? Not ones he is working on that are exempt from disclosure. I mean published reports.
MR. CARTMELL: I honestly need to check that because Jeff Kuntz will know that for sure.
MR. SNELL: Okay. Defense requests all published expert reports concerning slings, stress incontinence slings, and I'll go ahead and make the request for transvaginal mesh that you have published, not the ones that are in progress that are confidential, you know, subject to the work product, but ones you have actually published and have gone to the defense.
BY MR. SNELL:
Q. Is it generally accepted in your field, Doctor, that well-designed randomized control trials

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are the gold standard for directing clinical decision-making amongst different options that are studied?
A. Well designed?
Q. Yes, sir.
A. Well run, well randomized, randomized control trials, yes.
Q. For instance, why do groups like the Cochrane review look at randomized control trials?
A. They are a high quality of evidence, but what they do also is they look through the randomized control trials to make sure that they have a large enough sample size, they have appropriate methodology, their randomization technique was appropriate to determine whether or not they are going to add a randomized control trial to their systematic review.
Q. Is it your opinion that the difference in approach, bottom up to top down, is not responsible for the difference in bladder perforation rates as reported in Ogah where TVT had a lower rate than SPARC?
MR. CARTMELL: Same objections.
BY THE WITNESS:
A. I have seen a theoretical analysis that

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says that because the top-down approach you have dissected further into the retropubic space and the needle contacts the finger right through perforation of the fascial sheath that it protects the bladder from perforation. However, when you look at the data, specifically what was in the Ogah study, it shows that the bottom-up approach is associated with less bladder perforations.
BY MR. SNELL:
Q. How is that?
A. Theoretically?
Q. Let's start with theoretically, but I'm more interested in really how is that? But you can tell me theoretically first.
A. The bladder manipulator might do a better job of moving the bladder over to the side so that you have a lower chance of perforating the bladder.
Q. And when you say "the bladder manipulator", you mean when they put the cystoscope in there and turn it to the side or not?
A. No, you don't do that with a cystoscope. You do it with a rod that's placed -- and I'm forgetting the name of that instrument, but it's a rod that's placed into the Foley catheter to manipulate

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the bladder from one side to the other.
Q. Is the rod not placed through a Foley catheter in the design employed for the SPARC?
A. Since specifically today we are talking about the TVT, I've prepared to discuss the TVT. I am not prepared today to discuss the SPARC.
Q. Do you not know whether a rod is placed through a Foley catheter when carrying out a SPARC?
MR. CARTMELL: You can answer that if you know.
BY MR. SNELL:
Q. Yeah, I'm just asking your medical knowledge.
A. I don't recall that. Again, I've testified before that I've only done the TVT retropubic and not the SPARC procedure.
Q. Okay. So you would agree, then, that one potential benefit of the design of the TVT is that it uses a rod placed through the Foley catheter to mobilize the bladder in an attempt to minimize the risk of bladder perforation with the retropubic design, correct?
A. With the bottom-up approach?
Q. Yes, sir.
A. Specifically compared to the top-down

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approach?
Q. How about in general first?
A. What we do know is that bladder perforations happen between 5 and 15 percent of the time when we are doing a -- when one is doing a retropubic midurethral sling. The bladder manipulator is an instrument to help mobilize the bladder away from the trochar as it's being passed through the retropubic space, so that is the reason to -- if you will, that that component was designed.
Q. Utility and using the bladder manipulator, it attempts to minimize the risk or reduce the risk of bladder perforation when carrying out the retropubic TVT, correct?
A. That was the intention, yes.
Q. And it's also -- and you would agree there is utility to using the bladder manipulator during the TVT retropubic device?
A. As opposed to not using it?
Q. Yes.
A. Yes.
Q. You would agree that there is utility in using the bladder manipulator when carrying out the TVT retropubic as compared to using some other form of

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bladder manipulation, correct?
A. And when you are talking about another form of bladder manipulation, are you talking about another instrument or another technique?
Q. Either.
A. Well, I am not opining that there is a better design for bladder manipulation than the current embodiment. So, therefore, I don't -- I would say using a bladder manipulator is safer than not using a bladder manipulator.
Q. You would agree that part of the design of the TVT also -- strike that.
You would agree that part of the design of the TVT retropubic device to treat stress urinary incontinence also is the employment of using the cystoscopy to check the bladder, correct?
A. That is correct. There was a recent study that showed that with bladder perforation, the risk of mesh protrusion into the bladder was significantly higher than without bladder perforation.
Q. And is that study cited in your expert report anywhere?
A. I -- it is not cited in the expert report. It's probably on my reliance list.

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Q. You would agree that there is a benefit and utility to doing the cystoscopy when performing the retropubic TVT?
A. That is correct. If one sees the needle or the tape through the bladder, it is appropriate and within the standard to remove the needle and/or the tape from the bladder and then reposition the needle so that you are not in the bladder.
Q. What is the significance of a recognized bladder perforation during the time of retropubic TVT placement?
A. Well, as stated in the Osborne paper that came out in 2014, it used to be considered a rather innocuous event. However, looking at this data set, it would warrant another look at the risk of bladder perforation and subsequent placement of a tape lateral or in a different position to avoid bladder perforation since this paper suggests that there is a higher rate of bladder or urethral protrusion when -- at a remote time when the bladder is perforated during the accomplishment of a retropubic sling.
Q. And is the Osborne 2014 paper something you cite in your expert report?
A. Not in my expert report, no.

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Q. You mentioned that bladder perforation rates were 5 to 15 percent for retropubic midurethral slings.
That's something you mentioned before, correct?
A. That is correct.
Q. In your report, I didn't see it, but did you opine as to what the bladder perforation rate is pertinent to -- in particular to the retropubic TVT device?
A. Did I cite that in my report?
Q. Yes.
A. No, I did not.
Q. Have you formulated an opinion as to what is the bladder perforation rate with the Ethicon retropubic TVT device that treats stress urinary incontinence?
A. The specific number would fall into the range that I discussed.
Q. Can you -- can you -- is there a specific rate of bladder perforation with the Ethicon TVT device that you are holding as an opinion?
A. Is there a specific -- I hold the opinion of that it falls within that range that I quoted.

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Q. 5 to 15 percent?
A. That is correct.
Q. And what studies or data are you relying upon that opinion for?
A. I'm trying to find the exact number in the Ogah study, but reviewing all of the published literature, the rate of bladder perforation falls in the 5 to 15 percent range.
(WHEREUPON, a certain document was marked Rosenzweig Deposition Exhibit No. 3, for identification, as of 09/22/2015.)
BY MR. SNELL:
Q. Doctor, I've handed you Exhibit No. 3. And this is the most recent Cochrane review on midurethral slings. It is actually from the summer of July of 2015.
Have you ever seen this Cochrane review?
A. Yes, I have.
Q. I don't believe this is on your reliance list. When did you first review this paper?
A. Sometime after July of this year.
Q. Does this paper inform -- strike that.
Does the 2015 Cochrane review inform your

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opinions regarding the TVT retropubic device?
A. In what respect?
Q. In any respect.
A. Does this Cochrane review do what to any of my opinions?
Q. Inform your opinions, form the basis of your opinions regarding the TVT retropubic device?
A. This is another piece of literature that, again, I've reviewed and would help form my opinions, yes.
Q. I think I earlier misspoke. This is on your reliance list. So that is my apology and my bad.
A. I was pretty sure of it, but, you know, when you have as many citations on that reliance list, it is hard to know exactly what is there and what's not there.
Q. In this most recent Cochrane review, they report out, I was just looking for the rates of tape erosions --
A. Yes.
Q. -- and it says, the overall rate of vaginal tape erosion exposure extrusion was and we get over to 21 out of 1,000 in the retropubic group.
Do you see that?

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A. That is correct.
Q. So that would be a rate of 2.1 percent, correct?
A. That is what is quoted in this Cochrane analysis.
Q. And we were just talking about bladder perforation. If you look up above in the paragraph above it, I think you are probably familiar with this, where they did the metaanalysis on the rates of bladder perforation, they found that the rate with the retropubic slings was 4.5 percent.
Do you see that?
A. That is correct. And there is a range that it falls in, so it would fall in the range that I gave.
Q. All right. But this is what I would -- guess I should ask you then.
I understand you say that there is a range of 5 percent to 15 percent for the TVT retropubic device, correct?
A. That is correct.
Q. And, actually, if we want to be accurate and fair, there is actually a range reported in the literature that drops below 5 percent for bladder

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perforations for the TVT retropubic device, correct?
A. That is correct.
Q. All right. Fair enough.
My question then to you is:
Have you come to in your opinion a number which is the rate of bladder perforation specific to the TVT retropubic device?
A. It would fall --
Q. A single number, not falling between X and Y.
A. Well, again, there are a variety of different numbers that are published in all of the literature, not just in the randomized control trial, so I don't think that we are very far off in the rate that we're quoting. If we want to quote a 5 percent rate versus an 8 percent rate versus a 10 percent rate, I'm comfortable with any of those rates.
Q. You've read Dr. Blaivas, Dr. Iakovlev's review paper from 2015 regarding slings?
A. Yes, I have.
Q. In table 2 -- so you saw in the deposition where I took him through his own paper, correct?
A. Yes, you did.
Q. And table 2 for -- strike that.

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From table 3 of Dr. Blaivas' systematic review -- strike that.

In table 3 of Dr. Blaivas' reported systematic review of retropubic slings, he reports a rate of bladder perforation of 3.7 percent.

My question to you is:

Assuming what I just told you to be correct, 3.7 percent, would you disagree with that number as to what the overall rate is?

A. No.

Q. In table 3 also Dr. Blaivas reports that a rate of 2.2 percent for mesh exposure, erosion extrusion is applicable to the retropubic sling.

My question to you is, assuming what I just told you is correct and referenced in his study, would you agree or disagree with that number?

A. I would not disagree that that's what he quoted in his paper.

Q. Would you disagree with that number as being the accurate reflection of what the overall mesh erosion extrusion rate is with the retropubic TVT?

A. From the studies that he quoted. Now, we know that many of the studies in the literature are of a short duration and of a poor quality, from Petri's

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study complications -- the majority of complications show up 2 to 5 years after the mesh is placed. So 60 percent of the complications show up after that time. So while that might be the number that's reported in the literature, more likely than not it is a lower end of what the true rate of complications are.

Now, bladder perforations I would say is a much more accurate number because you will know that at the time of surgery with a reasonable degree of medical assuredness. But if you are quoting a study where the vast majority of the studies that are published in the literature have one-year follow-up, the vast majority of complications from slings will not be seen. 80 percent of them will not be seen until after one year.

Q. Well, actually, Doctor, it's correct that his 2.2 percent mesh exposure erosion rate for retropubic TVT could be an overestimate based on the literature?

MR. CARTMELL: Object to the form, lacks foundation, calls for speculation.

BY THE WITNESS:

A. No.

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BY MR. SNELL:

Q. Here is the foundation.

You saw, Doctor, that I had to show Dr. Blaivas numerous long-term studies that he didn't account for, correct?

A. I think you showed him three studies that he didn't account for.

Q. I showed him a five-year randomized control trial on TVT?

A. Yes.

Q. And that's long-term, correct?

A. Five years would be -- five to ten years is long-term.

Q. And I showed him the Serati TVT retropubic 10-year paper, correct?

A. That is correct.

Q. And I showed him the Heinonen 10.5 year TVT retropubic study?

A. And that study showed a bladder erosion at nine years that required at least two surgeries to fix, yes.

Q. Okay. So focusing on mesh exposure with TVT --

A. Yes.

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Q. -- and erosion, by Dr. Blaivas not including those long-term studies that reported there was a lack of mesh erosion and exposure at long-term, Dr. Blaivas actually very well may have overstated the rate of TVT mesh erosion extrusion, correct?

MR. CARTMELL: Object to the form.

BY THE WITNESS:

A. Again, the majority of complications show up according to Petri's, Agnew's analysis, Marcus-Braun's analysis show up more than one year after the implantation of the sling. And, therefore, many of the other studies that are quoted in the literature would miss those complication rates. Dr. Blaivas missed three long-term studies, and so while those might -- and if I remember correctly, the total number of patients in those studies was around 300, the vast majority of the women that have had midurethral slings with only one-year follow-up or two-year follow-up, the majority of their complications would have gone missed.

MR. SNELL: Move to strike as non-responsive.

BY MR. SNELL:

Q. This Petri study that you referenced that I haven't asked you about, I'm going to ask you about

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it now, and we'll pull it later, does the Petri study say that it's a good thing or a bad thing to have data beyond one year?
A. It's a good thing.
Q. And you would agree Dr. Blaivas missing five- and ten-year long-term TVT data is a bad thing, correct?
MR. CARTMELL: Object to the form of that. It calls for speculation, lacks foundation.
BY THE WITNESS:
A. I think you discussed that with Dr. Blaivas during his deposition.
BY MR. SNELL:
Q. But you would agree that's a bad thing he missed that long-term data, correct?
MR. CARTMELL: Object to the form, lacks foundation, calls for speculation.
I don't think Dr. Blaivas admitted that he missed anything. So that's a misstatement of the testimony. I think the testimony was that he'd have to talk again to the authors about whether or not they decided intentionally not to include it, isn't that correct?
MR. SNELL: Objection; speaking objection.

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That's malarkey.
MR. CARTMELL: Is that not true?
MR. SNELL: That's not true. That's malarkey. He went back and tried to find some goofy justification and I called him on those too.
MR. CARTMELL: But he didn't say he missed it, and you are saying that he missed it, so we can't --
MR. SNELL: I'm saying he missed including it in his analysis.
MR. CARTMELL: It doesn't include it, but that doesn't mean that they didn't decide not to include it.
BY MR. SNELL:
Q. You would agree that it's a bad thing that Dr. Blaivas did not include that longer term data on the TVT device in trying to formulate a systematic review, correct?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. As discussed in his deposition, those three studies were not on his reference list.
BY MR. SNELL:
Q. Do you agree that's a bad thing?
MR. CARTMELL: Object to the form.

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BY MR. SNELL:
Q. You can either agree, disagree or say I don't have an opinion, and then I'll move on, but I'm entitled to an answer.
A. I don't have an opinion.
Q. Fair enough.
What was the device that was studied in the Petri study?
A. They were midurethral slings.
Q. How many of the cohort were TVT retropubic slings?
A. If you have a copy of the Petri study, we can talk about the numbers that were TVT retropubics.
Q. As you sit here, you don't recall?
A. The exact number, no.
Q. We'll try and pull that and we'll just circle back around to this, if that's okay with you.
A. Sure.
Q. I don't want to waste time with something until we get it in front of us then.
Is it desirable in your field to have randomized controlled trials upon which to base clinical decisions for the treatment of stress urinary incontinence?

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MR. CARTMELL: Same objection.
BY THE WITNESS:
A. Randomized controlled trials are useful in evidence-based medicine and making decisions about the treatment of patients.
BY MR. SNELL:
Q. And that includes the intended treatment of stress incontinence, correct?
A. That is correct.
Q. You would agree that the use of the sheath in the design of the TVT retropubic device provides a benefit or utility?
A. The sheath specifically?
Q. Yes.
A. Yes.
Q. Tell me what benefit and utility the use of the sheath in the TVT retropubic device provides?
A. Without having a sheath, you can tear tissue when pulling the mesh material through the retropubic space. It can -- it's been theorized that it helps decrease the amount of bacteria that are picked up on the sling material.
Q. Are there any -- are there benefits or utility to the use of the sheath in the TVT retropubic

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design?
A. There might be other theoretical advantages. Those would be the main ones.
Q. What are those other theoretical advantages?
A. I said there might be. I don't recall right sitting here.
Q. Okay. You don't have an opinion on any other ones?
A. No.
Q. Well, let me ask you this:
Because you have placed the TVT retropubic device, correct?
A. Yes.
Q. Tell me how you found the sheath useful in the design of that device when you used it?
A. Again, there -- when placing the TVT device, there was less drag when going through tissue.
Q. What other benefits or attributes did you notice when you personally used the sheath in carrying out placement of the TVT retropubic device?
A. That was the main attribute.
Q. How does dragging a sling through the tissue without the sheath -- strike that.

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So if I'm understanding you, pulling the TVT retropubic device by way of its design to have gone through the tissue but without the sheath can tear the tissue you said?
A. Yes.
Q. And that's obviously an unwanted occurrence, correct?
A. Yes.
Q. Are there any other unwanted occurrences by dragging the mesh without the sheath on it through the tissues?
A. That would be the main one.
Q. As you sit here today, can you think of any other unwanted outcomes of not utilizing the sheath?
A. Again, the theoretical that while you're pulling the tape through the sheath could protect against bacteria getting on the mesh.
Q. Does using the sheath in the design of the TVT also protect the shape of the mesh sling when it's pulled through the tissue?
A. No.
Q. Have you ever actually held the TVT retropubic device on the sheath and tried to pull it

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and change or alter the shape of the mesh?
A. Hold the sheath and pull on the tape?
Q. Yes, hold, clamp and hold onto -- on top of the sheath with the mesh underneath -- let's back up.
The sheath sits on the outside of the mesh tape, correct?
A. That is correct.
Q. At the end it is attached to trochars, correct?
A. No. The mesh is attached to trochars.
Q. Fair enough.
Now, my question is, have you yourself clamped the -- with your hands or some other instrument, clamped the sheath of the TVT retropubic device while the mesh is inside?
A. The body?
Q. No. Inside the sheath.
A. Yes.
Q. And tried to alter the configuration of the mesh?
A. Well, while --
MR. CARTMELL: Object to the form. I think it's vague and ambiguous, what you mean by tried to alter

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the configuration.
BY THE WITNESS:
A. During the implantation process it is recommended not to put an instrument on the TVT until it is through the skin incisions.
BY MR. SNELL:
Q. Why is it important to not put an instrument on the sheath until the mesh is through the skin incisions?
A. Well, to clamp it, you can potentially damage the mesh itself.
Q. So I guess my question to you, and I want to back up and see, have you ever held in your hands or clamped on a machine the TVT mesh and the sheath?
A. I have not. But you know that the sheath is separated in the center.
Q. Yes.
A. So it is not one contiguous thing. So if you clamp the sheath onto the mesh and you pull it, it's going to separate the -- you are going to pull on the mesh.
Q. How about this:
So the separation of the sheath is in the middle, as I understand it. Is that consistent with

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your experience?
A. That is correct.
Q. All right. So if we take and we call them -- can we call it a left and a right half that's under sheath?
A. Yes.
Q. If you were to take part of the left half of the mesh that's under sheath and clamp it with your hands or a machine and try to pull it and stretch it, what would happen?
A. Eventually you would get to the burst point of the plastic and then you would just continue to elongate the mesh. So you would elongate the sheath and the mesh.
Q. So has anyone done that testing that shows at what point and how much force is required to elongate not only the mesh but the sheath, too, when the mesh is still in the sheath?
A. Well, remember that the sheath is not attached to the trochar. So when you pull the trochar through, you are actually putting pressure on the mesh and not the sheath.
Q. Okay.
A. So have I seen anybody describe the burst

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point of the sheath itself?
Q. The sheath itself that shows at what point the force is if clamped on the mesh while the sheath is remaining on top of the mesh, at what point that will cause the sheath to tear and the mesh to deform?
MR. CARTMELL: Object to form.
BY THE WITNESS:
A. I have not seen that reported in any of the documents that I've looked at from Ethicon.
BY MR. SNELL:
Q. Okay.
MR. CARTMELL: I think lunch is here.
MR. SNELL: Is it?
MR. CARTMELL: I think so, if you guys are ready.
MR. SNELL: Yes. That's good for me.
(WHEREUPON, a recess was had from 12:21 to 12:57 p.m.)
BY MR. SNELL:
Q. Before lunch, so we are back after lunch, before lunch we were talking about the Ogah Cochrane review and some other data that you had considered, correct?
A. Yes, sir.

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Q. Let's see if we can summarize our discussion.
As you sit here today, you cannot tell me of any difference in design that would account for the statistically significant better efficacy seen with TVT compared to SPARC, correct?
MR. CARTMELL: Same objections as previously stated with respect to comparisons with the SPARC.
BY THE WITNESS:
A. Specific comparisons, no.
BY MR. SNELL:
Q. In your report you do not specify what the overall rate of mesh exposure is for the TVT retropubic design, correct?
A. In my report I do not quote a number, no.
Q. Have you formulated an opinion as to what the overall rate of mesh exposure is with the TVT retropubic device?
A. Well, we've talked about some numbers earlier today, and I think that those numbers are grossly underestimated. Many of the studies that we have -- we looked at, we talked about are short-term efficacy studies that don't look at complications. Some of the long-term studies that have been published

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in the literature are phone interviews or surveys that are mailed to patients that cannot capture whether or not they are having an erosion that might not be clinically symptomatic. I think that many investigators, including Ogah have stated that it is very difficult to know what the true rate of long-term complications are because of underreporting of short-term papers, of poor study design where the studies are not designed to -- to look at long-term complications. And so I think while the numbers that we talked about are estimates, I would say that the complication rate for erosion is much higher than 2, 3, 4 percent, probably higher than even 10 percent.
MR. SNELL: I'm going to move to strike as non-responsive.
BY MR. SNELL:
Q. My question was this:
Have you formulated an opinion as to what the overall rate of mesh exposure is for the TVT retropubic design?
MR. CARTMELL: Objection; asked and answered. That's what he just told you.
MR. SNELL: I don't think so. I think that there was literally like a long discussion about all

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kinds of stuff. It's a yes -- it's a yes, no or I don't have an opinion.
MR. CARTMELL: Oh, well, he answered it yes and then gave you his opinion.
MR. SNELL: No, he didn't say yes at all. He said, well, we've talked about numbers today and then the discussion goes on and on and on and on.
MR. CARTMELL: You just want to know if he has an opinion? But he told you the opinion. He just didn't answer the --
MR. SNELL: He is non-responsive, right. That's my objection, non-responsive.
BY THE WITNESS:
A. Yes.
BY MR. SNELL:
Q. Thank you.
So you have an opinion about the rate of mesh exposure for the TVT retropubic device?
A. Yes.
Q. And why did you not include that opinion in your expert report?
A. The specific number?
Q. Yes.
A. Of what -- the -- what my opinion of the

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erosion rate is?
Q. Yes.
A. In my report I did not put specific numbers for any of the complications associated with TVT retropubic.
Q. Fair enough.
What effect, if any, did pore size have on TVT's statistically significant lower rate of voiding dysfunction compared to SPARC?
MR. CARTMELL: Same objections with respect to comparisons to SPARC.
BY THE WITNESS:
A. Again, that would go to things that are in reports and that have protective orders associated with it.
BY MR. SNELL:
Q. So it would be in reports that you -- that I don't have, correct?
A. Well, not a direct comparison, no.
Q. You didn't bring the SPARC reports to the deposition today, correct?
A. That is correct. I'm not sure that they've been published yet.
MR. CARTMELL: Let me do this. I don't care if

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this is on the record or not, because I don't want to scare him away from answering things. I don't think he can answer things based on protected information related to the SPARC, but if your question was just based on the Ogah study, is that what your question was based on?
MR. SNELL: That's what -- yes. I mean, it's really coming from the Ogah study, right.
MR. CARTMELL: Then I do think you can answer --
MR. SNELL: I can ask this preface -- let's preface it with this, okay, just so...
BY MR. SNELL:
Q. Are you aware of any other randomized control comparator studies between TVT and SPARC besides the ones included in the Ogah study or the Ford more recent Cochrane review?
A. There might be one or two other studies that weren't included.
Q. As you sit here today, can you tell me what they are, if they even exist or are you essentially guessing?
MR. CARTMELL: Object to form.
BY MR. SNELL:
Q. I'm not trying to be smart or anything.

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I'm serious.
MR. CARTMELL: He just told you there may be one or two.
BY MR. SNELL:
Q. There may be one or two more.
Are there one or two more or are you guessing that there may be one or two more?
A. Well, knowing the methodology used in the Cochrane analysis, they would not include lower quality randomized control trials or comparative studies. I would envision that there are other comparative studies that were not included in the Ogah analysis.
Q. So can you tell me what effect, if any, did pore size have on TVT's statistically significant lower rate of voiding dysfunction compared to SPARC?
A. SPARC has a smaller pore size than TVT retropubic.
Q. And that's not some secret confidential information, correct?
A. That is correct.
Q. That's out in the literature, it's in published materials, on the websites, correct?
A. That is correct.

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Q. Okay. And how did the smaller pore size of SPARC lead to higher voiding dysfunction compared to TVT?
A. Well, smaller pore size increases bridging fibrosis, increasing mesh contraction. And, therefore, as the mesh contracts it becomes under tension and leads to voiding obstruction.
Q. What effect, if any, did the way the mesh was cut have on TVT's significantly lower rate of tape erosion compared to SPARC?
MR. CARTMELL: Same objections.
BY THE WITNESS:
A. There is no difference in the method of cutting.
BY MR. SNELL:
Q. Okay. What effect, if any, did the stiffness or elasticity have on TVT's significantly lower rate of tape erosions compared to the SPARC?
MR. CARTMELL: Same objection.
BY THE WITNESS:
A. SPARC is stiffer than TVT.
BY MR. SNELL:
Q. What effect, if any, did the stiffness or elasticity have on TVT's lower rate of voiding

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dysfunction compared to SPARC?
A. TVT -- SPARC is stiffer than TVT.
Q. Are you saying that because SPARC was stiffer than TVT that's what caused more tape erosions and voiding dysfunction?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. Stiffness contributed to tape erosions, small pore size would lead to mesh contraction, foreign body reaction, but there is overlap between -- there are only certain kinds of complications that can happen in the vagina. When you look at stiff mesh, stiff mesh, as we talked about several times before, leads to cytotox- -- or apoptosis and cell death. So a stiffer mesh is going to lead to more cell death than a less stiff mesh. Smaller pore size is going to increase the amount of bridging fibrosis and scarring which will then lead to more mesh contraction.
MR. SNELL: I'm going do move to strike as non-responsive. I don't think I got an answer to my question.
Can you read back the question?
(WHEREUPON, the record was read by the reporter as requested.)

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MR. CARTMELL: Before you answer it, so I'm clear, are you still talking about in the studies that are identified in -- because there has been no --
MR. SNELL: Yes, yes.
MR. CARTMELL: -- identification what studies you are talking about in this line of questions.
MR. SNELL: Yes. This is the Cochrane review.
MR. CARTMELL: The 2011 Cochrane review studies?
BY THE WITNESS:
A. This information I'm giving you is not from the Cochrane review.
BY MR. SNELL:
Q. Okay. So --
A. That's not in the Cochrane review.
Q. Okay.
MR. CARTMELL: We did not offer him as an expert to give opinions that the TVT is safer than the SPARC or more dangerous than the SPARC.
BY MR. SNELL:
Q. I'm asking about the data, the results that showed up in the Cochrane review that you cited to and relied upon.
A. Yes.
Q. And I'm asking you about the design of TVT

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and how things that you've talked about in putting your report, like pore size, stiffness, how that comes to bear on complications in the rates. So I am talking about Ogah.
A. But that's not in -- that discussion is not in Ogah.
Q. About exactly how pore size affected the numbers?
A. Right. That's in my report.
Q. Exactly. Okay. So I think we are communicating.
MR. SNELL: I don't know what you don't understand, Tom.
MR. CARTMELL: Well, he has given these opinions about pore size affecting erosions and things like that, but you were saying in your questions, I thought, and you just confirmed, that what in Ogah would account for the SPARC erosions being more related -- more than TVT.
MR. SNELL: My question --
MR. CARTMELL: Hold on. And saying --
MR. SNELL: I didn't say that. That wasn't my question.
MR. CARTMELL: Without giving him studies, I'm

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just lost.
BY MR. SNELL:
Q. My question was, what effect, if any, did the pore size have? All right.
MR. CARTMELL: In what?
MR. SNELL: Do you want me to repose? I've already asked these questions.
MR. CARTMELL: What effect, if any, did the pore size have in what? In the studies?
MR. SNELL: No, no, no. That's a speaking objection.
BY MR. SNELL:
Q. What effect, if any, did the weight of the mesh have in leading to TVT's statistically significant lower rate of tape erosions compared to SPARC?
MR. CARTMELL: And you are saying in the Ogah study?
MR. SNELL: Oh, my God, Tom.
MR. CARTMELL: Do you have the study so he can look at them?
MR. SNELL: I have it. I have it. I have Ogah. I'm asking him what effect, if any. It is a straight forward question.

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BY MR. SNELL:
Q. So go ahead.
A. There is no difference in weight between SPARC and TVT.
Q. So do you believe that weight had any effect whatsoever on any of the differences seen for TVT versus SPARC?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. Weight in and of itself?
BY MR. SNELL:
Q. Weight of the mesh.
A. No, because they both have the same weight.
Q. What effect, if any, did the inflammatory response have on the lower rate of tape erosion with TVT compared to SPARC?
MR. CARTMELL: Same objections.
BY THE WITNESS:
A. What effect did the inflammatory response?
BY MR. SNELL:
Q. What effect, if any, did the inflammatory response have on the lower rate of tape erosion seen with TVT compared to SPARC?

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A. A smaller pore mesh will have a higher inflammatory response than a larger pore mesh.
Q. So are you saying that the SPARC had a high -- a greater inflammatory response than the TVT retropubic device?
A. I'm saying that SPARC has -- it is a stiffer mesh and has a smaller pore size than TVT. Smaller pore size increases inflammation, increases chronic foreign body reaction, increases bridging fibrosis and scarification. All of which is in my report and all of which you and I have discussed before.
Q. But we haven't gotten down to this level of detail, which is -- let's see if we can make this straight forward.
So we know TVT had a significantly lower rate of tape erosion compared to SPARC. We've already established that, correct?
MR. CARTMELL: Object to the form. Are -- you need to be clear. If you are talking about in Ogah or in some other study or in general, it needs to be clear, Burt.
BY MR. SNELL:
Q. Did you understand my question or do I

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need to repeat it or rephrase it?
A. Can you rephrase it?
Q. Sure, sure.
So we've been discussing the differences seen between TVT and SPARC with regard to the complications reported in the Ogah paper, correct?
A. That is correct.
Q. All right. And we've talked some about pore size, stiffness, weight, inflammatory response, those characteristics of the mesh, correct?
A. Correct.
Q. Of the different meshes, correct?
A. Of between those two meshes, yes.
Q. There we go.
And so for tape erosion I wrote down that you believe that pore size played a role, correct?
A. Pore size played a role, yes.
Q. And for tape erosion, you also wrote that the inflammatory response would have played a role?
A. That is correct, which is related to pore size.
Q. Right. The stiffness with SPARC being -- strike that.
SPARC being more stiffer than TVT, you did

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not attribute that to playing a role in tape erosions, did you?
A. Yes, I did.
Q. Oh, you did, okay.
MR. CARTMELL: Same objections.
BY MR. SNELL:
Q. I don't want to mis- -- I'm serious, I'm trying to get this.
Was there anything else that played a difference in your opinion on -- strike that.
Was there anything else besides that that you identified that played a role in the difference of tape erosion reported in the Ogah study?
A. Without getting into confidential materials, no.
Q. And you are not prepared to discuss these confidential materials or issues today?
A. No.
Q. So this is the question I have then.
So focusing on the three factors that you will identify for me today as playing a role, pore size, inflammatory response and stiffness, how much -- how much do each of those account for the difference seen in tape erosion rate? Do you understand me?

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MR. CARTMELL: Object to form.
BY THE WITNESS:
A. How much does each of them play?
BY MR. SNELL:
Q. Play or account for. Maybe I can ask the hypothetical. It will kind of --
A. Okay.
Q. So, if the rate of tape exposure with TVT is 2 percent and the rate with SPARC was 6 percent, there being a 4 percent difference, correct?
MR. CARTMELL: Yeah, do you want him to look at the --
MR. SNELL: No. This is a hypothetical.
BY THE WITNESS:
A. Oh, hypothetically speaking, all right.
BY MR. SNELL:
Q. Yeah, hypothetically speaking.
So if TVT has a rate of -- hold on. Now you are making me look because maybe the number is right in here.
No, I don't see it in here. Let's just go with the hypothetical.
So hypothetically if the rate of tape erosion with SPARC was 5 percent and the rate with TVT

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was 2 percent, and that was statistically significantly higher as reported in Ogah, how much -- or better yet, can you say how much the pore size played in that difference seen between those two meshes?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. We know that looking at a smaller pore mesh, such as GYNEMESH PS, versus a larger pore mesh, Ultrapro, there are 50 percent fewer erosions and 50 percent fewer complications with the larger pore mesh. So 50 percent of the change -- the change in pore size can account for approximately 50 percent of the erosions.
BY MR. SNELL:
Q. The study and data you are referencing is a paper that did not include the TVT retropubic device, correct?
A. Well, that is, again, we are just discussing pore size right now, okay. And you asked -- you didn't say in your hypothetical that we're talking about specifically the -- what's quoted in the Moalli paper of the TVT pore size which is 13.76 and certain internal documents it is 1100 for

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the larger pores, 300 for the smaller pores for the TVT, SPARC being less than a millimeter in size.
What I'm describing is when you look at a different -- between different meshes of pore size, you see a 50 percent reduction in erosions with a larger pore mesh. So extrapolating that, a -- the greatest amount of improvement in erosion rate from a theoretical larger pore would be 50 percent, in your hypothetical situation.
Q. And but just so the record is clear too, the study you were referencing to make that hypothetical extrapolation was not a study involving the TVT device, correct?
A. That is correct. But it is a study that looked at the difference between different pore sizes.
Q. Including Vypro which is the largest pore size, correct?
A. This study did not include Vypro.
Q. Okay. That study included Ultrapro and Prolene Soft?
A. That is correct.
Q. And you don't recall category No. 1 being Vypro in the Okulu study?
A. Oh, I wasn't referencing the Okulu study.

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Q. Okay. So which one were you talking about?
A. I was talking about the an Lynette study, but if you want to talk about the Okulu study, yes, that was Ultrapro versus GYNEMESH PS for a sling and there were fewer erosions in the -- with the sling made of Ultrapro.
Q. So the study you were referencing was which one?
A. It's the Lynette, part of the Milani papers.
Q. Is that identified in your report?
A. Is that on this reliance list? No, not that I'm aware of.
Q. The Okulu study which is the one that I thought you were talking about, that's the one that looked at Vypro, Ultrapro and Prolene Soft, right?
A. Right, and you and I have had a discussion about why Vypro has significant --
Q. So I don't have to ask you that again.
A. Excellent.
Q. But we can agree that in Okulu they did not use the TVT retropubic device, correct?
A. That is correct.

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Q. They didn't use sheaths, correct?
A. That is correct.
Q. They didn't place it tension-free, correct?
A. If you have the Okulu study, I'd -- to look at, I can answer that question about tension.
Q. Do you recall they tied the sutures off up top in the Okulu study in the way that they performed that placement?
A. Just by tying the sutures that doesn't mean that it was placed under tension.
Q. Let's give him the study just so we are clear.
(WHEREUPON, a certain document was marked Rosenzweig Deposition Exhibit No. 4, for identification, as of 09/22/2015.)
BY MR. SNELL:
Q. So on page 219 of Exhibit 4, the Okulu study, they report on their operative technique, correct?
A. That is correct.
Q. And there are a lot of differences between that technique and the TVT retropubic technique,

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correct?
A. That is correct, but it does not say that they placed it under tension.
Q. Including, let's see, they made an A-shaped incision -- inverted A-shaped incision to the interior vaginal wall, correct?
A. That is correct.
Q. You don't do that with the TVT, correct?
A. That is correct.
Q. And then they made some patch that was 3 by 4 centimeters in most patients, correct?
A. That is correct.
Q. And that is not done with the TVT, correct?
A. That is correct.
Q. And if we look down, it talks about all of the different tools and Kishner needles, prolene sutures that were used, correct?
A. Yes.
Q. What are Kishner needles and how do they compare to Stamey needles that I've heard of?
A. I have not used a Kishner needle, but I would assume that it was similar to a Stamey needle.
Q. It says, "After confirmation that the

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bladder and urethra were normal, the prolene sutures were ligated crosswise in the suprapubic region," correct?
A. That is correct.
Q. What does that mean?
A. That the sutures were tied to one another.
Q. Up top in the -- above the rectus fascia?
A. That is correct.
Q. "Special attention was paid not to create much tension on the mesh material."
Do you see that?
A. That is correct.
Q. Do you know what methodology they would have used to not create much tension on the mesh material when they utilized the tying off of the prolene sutures?
A. It was probably the similar methodology used to avoid tension with the TVT.
Q. Dr. Blaivas testified that when he does his autologous slings, he'll put a single finger breadth and tie the sutures over top.
Do you recall seeing that?
A. Yes.
Q. Is that how -- withdrawn. I think you and

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I have covered this before.
A. That is correct.
Q. So your earlier testimony, I think it was one or two depositions ago, about how you view obstruction of the lumen of the urethra is the methodology by which you tension your fascial slings?
A. Yes.
Q. That hasn't changed?
A. And I tell my patients that they have a higher risk of voiding obstruction because of the way I do it because they have a much more severe form of stress urinary incontinence.
Q. But you haven't changed the way you tension your fascial slings, correct?
A. No.
Q. Okay. In Ogah, do you have that Ogah paper?
A. Yes.
Q. They report that monofilament tapes like the TVT has significantly higher objective cure compared to multifilament tapes and fewer tape erosions.
Do you see that?
A. What page are you --

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Q. This is on the very front of Exhibit 2 in the Background and the Results section in particular.
A. Yes.
Q. Now, have you also cited to that portion of the Cochrane review in an expert report?
A. Regarding multifilament tapes versus monofilament tapes?
Q. Yes, sir.
A. And there is higher objective cure rates compared to multifilament tapes and fewer erosions?
Q. Yes.
A. I've referenced the Ogah analysis but not that specific phraseology.
Q. Do you agree or disagree with that conclusion coming out of Ogah that multifilament tapes had a higher objective cure compared to multifilament tapes?
MR. CARTMELL: I think you misspoke?
MR. SNELL: Did I? Okay. I can clean it up. I want to break it down and not have it compound.
BY MR. SNELL:
Q. Do you agree with Ogah's reporting that monofilament tapes had a significantly higher objective cure rate than the multifilament tapes?

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A. That was statistically significant according to their review.
Q. Is that consistent or inconsistent with your opinions?
A. That is consistent with my opinions.
Q. And the monofilament tapes have fewer tape erosions compared to the multifilament tapes in Ogah, correct?
A. That was not statistically significant.
Q. It was 1.3 versus 6 percent, correct?
A. Yes, but the confidence interval crossed 1, touched and crossed 1, so that's not statistically significant.
Q. Do you believe that the multifilament tapes have more tape erosions than monofilament tapes?
A. That's what Ogah says and their data shows a 1.3 versus a 6 percent. I don't think my opinion is inconsistent with that.
Q. You are aware that Petros and Ulmsten analyzed different types of mesh, like Mersilene, before determining to use the prolene mesh in TVT?
A. Mersilene is a multifilament mesh.
Q. But the answer to my question is, yes, you are aware of that?

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A. Yes.
Q. And is it correct that it was state of the art when TVT was designed to treat stress incontinence to use a monofilament mesh?
A. It was?
Q. State of the art.
MR. CARTMELL: Objection to form. Sorry.
BY THE WITNESS:
A. If there is that quote, I would like to see the paper where that is it quoted from.
BY MR. SNELL:
Q. I'm not asking you for a quote. I'm asking you, was it state of the art when TVT was designed to use a monofilament mesh for the intended use of treating stress urinary incontinence?
MR. CARTMELL: Object to the form.
Do you understand what state of the art means?
BY THE WITNESS:
A. Yeah, I'm -- that's what I'm having -- you know, can you --
MR. CARTMELL: If you don't understand, you need to tell him.
BY THE WITNESS:

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A. Yes, can you define for me what you mean by state of the art?
BY MR. SNELL:
Q. How about this, you tell me, what is state of the art in your field of stress urinary incontinence surgery?
MR. CARTMELL: Object to form.
BY MR. SNELL:
Q. When that term is used, something being state of the art, what does it mean?
MR. CARTMELL: Object to form.
BY THE WITNESS:
A. I think different people have different meanings and, therefore, they should define them so that people know what they mean by state of the art.
State of the art could imply talking about all of the embodiments that are out there, state of the art could be that this is a unique embodiment, state of art could be that this is the preferred embodiment, so.
BY MR. SNELL:
Q. How about this, state of the art, that's going to be the highest level of general development of a device in your field at that particular time?

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A. I would not agree with that.
Q. Okay. And why would you say that?
A. Well, first of all, the device had just been "pioneered". We know in 1999 that right before the device was coming onto market that Ethicon had already started a TVT improvement project because of problems that were noted with TVT: sharp edges, the risk of erosion, the risk of particle loss. And, therefore, it's very difficult to say something is the -- what was the quote again?
Q. State of the art --
A. No. The highest level of?
Q. State of the art refers to the highest level of general development of a device at a particular -- pertinent time.
A. Right. So if they are already starting to modify the device, as I've stated in my report, it's very difficult for it to be state of the art if they are already finding that the embodiment has significant defects associated with it which can lead to harm to patients.
MR. SNELL: I'm going to move to strike. I don't think that that's responsive.
BY MR. SNELL:

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Q. Do you -- let me ask you this then.
Do you believe that any time a device manufacturer looks at improving or altering their product, that means that the then existing product is defective or deficient in some manner?
A. If they are improving a defect, then the device is defective. If it's a defect that will cause harm, a device is defective. So if you have a patient that's developing pain from sharp edges, you have particles falling off that can erode through the vagina, if you are having difficulty tensioning the device and you are talking about developing a spacer device so that tensioning which is very critical to this to avoid a voiding obstruction, overactive bladder, urethral erosion, yes.
Q. You mentioned pain -- let me back up and get back to my question.
When TVT was designed, what was the preferred type of mesh to use for the treatment of stress urinary incontinence as between monofilament or multifilament?
MR. CARTMELL: Object to the form. It misstates the evidence.
Are you talking about the time TVT first

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came to market and was the first product for SUI?
MR. SNELL: When it was designed. I'm focusing on the design factor for the intended use.
BY MR. SNELL:
Q. When TVT was designed, what was the --
MR. SNELL: What did I say, can you read the question back.
(WHEREUPON, the record was read by the reporter as requested.)
MR. CARTMELL: Object to the form.
BY MR. SNELL:
Q. Can you answer that question?
A. There was no preferred embodiment of monofilament versus multifilament.
Q. When was it that monofilament mesh for the treatment of stress urinary incontinence for a midurethral sling became desired?
MR. CARTMELL: Object to the form, misstates the evidence.
BY THE WITNESS:
A. When did a monofilament midurethral sling first become desired?
BY MR. SNELL:
Q. So, let me back up.

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A. After it was marketed by Ethicon.
Q. That's fine, but I'm actually asking for a scientific opinion, not some marketing opinion.
A. Well, and that is a marketing opinion.
Q. I'm not being smart.
A. Very shortly before -- or right after the device came out, marketing was already talking about making this the -- making this device the gold standard. So it was marketing that drove this to becoming the, quote/unquote, as your question was, the preferred embodiment of a monofilament midurethral sling. Before that slings were placed at the bladder neck as pubovaginal slings.
Q. I know. I know all of that, but that's not responsive to my question. My question is focused on the science.
You told me that in your opinion there was not a preference for monofilament over multifilament at the time TVT was designed, correct, or did I mishear you?
MR. CARTMELL: No. You heard him.
BY THE WITNESS:
A. No. There was -- Gore-tex was used, Mersilene was used, Marlex was used. There were a

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variety of different embodiments to -- that were used to treat stress urinary incontinence as a pubovaginal sling.
BY MR. SNELL:
Q. And you had seen in the literature that Gore-tex had been reported to have rates of mesh exposure higher than 10 percent in the application of treating stress urinary incontinence, correct?
A. Yes, but remember it was placed in a different way in a different fashion. It was purposely placed under tension to treat recurrent severe stress urinary incontinence.
Q. And you had seen reports in the literature where Mersilene as used to treat in the application of stress urinary incontinence had more than 10 percent rates of mesh exposure too, correct?
A. That is correct.
Q. And that was not under a different implantation technique, that was actually at the midurethral by Petros, correct?
A. If you have that specific report by Petros to look at, I would appreciate seeing that so I can give you an honest, complete and sincere answer.
Q. How about this, as you sit here today, I

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know you made the caveat about Gore-tex and its intended use for stress urinary incontinence --
A. As a pubovaginal sling.
Q. -- as a pubovaginal sling.
Before TVT was brought to market, Mersilene had been reported in the application of stress urinary incontinence to have 10 percent or higher rates of mesh exposure, correct?
A. Do you have that study so I can take a look at it?
Q. I don't have it on me to be honest with you.
A. Then I can't answer that question.
Q. You don't know one way or the other?
A. You are talking about a very specific paper that you don't have on you, so I can't look at that to be able to discuss that specific number that you gave me.
Q. I'm not asking you about a specific study. I'm saying in your review of the literature, and you know the literature prior to TVT being brought to market, prior to 1998 there were reports in the medical literature that Mersilene had a rate of exposure more than 10 percent when utilized for a --

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as a sling to treat incontinence?
A. But you said utilized as a midurethral sling.
Q. Okay. Let me just drop that. I want to get to the more basic question.
A. We know from the Ogah analysis that multifilament tape had a higher erosion rate of approximately 6 percent. So we can use that as a more modern number.
Q. I'm interested in before TVT.
So you are aware from reviewing the medical literature and practicing in the field, before TVT came to market in 1998 -- hold on, I get to ask the questions --
A. Okay.
Q. -- that Mersilene had been reported to have mesh exposure rates of higher than 10 percent in the literature?
A. If you are talking about pubovaginal slings, we have to talk about the application because we are not -- you know, these could have been placed just like I placed Gore-tex slings under more tension to treat recurrent severe stress urinary incontinence which is going to have more complications because it

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is treating a different group of patients.
MR. SNELL: Move to strike as non-responsive.
Can you read the question back?
(WHEREUPON, the record was read by the reporter as requested.)
MR. CARTMELL: Asked and answered.
BY THE WITNESS:
A. For pubovaginal slings placed at the bladder neck under tension to treat recurrent severe stress urinary incontinence, yes.
BY MR. SNELL:
Q. So the answer is yes? I was just looking for a yes. I'm fine with your caveats, but you gave me a yes there?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. Yes.
MR. SNELL: Why don't we take a break.
(WHEREUPON, a recess was had from 1:41 to 2:01 p.m.)
BY MR. SNELL:
Q. So we were talking before we took a break about the use of different meshes and the intended application of stress urinary incontinence before TVT

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was brought to the market.
I want to hand you a study.
(WHEREUPON, a certain document was marked Rosenzweig Deposition Exhibit No. 5, for identification, as of 09/22/2015.)
BY MR. SNELL:
Q. Doctor, we've marked as Exhibit No. 5 a paper published in 2001, the lead author is Falconer, regarding the Influence of Different Sling Materials on Connective Tissue Metabolism in Stress Urinary Incontinent Women.
Do you see that?
A. Yes.
Q. Is this the paper that you've read and you are familiar with?
A. Yes.
Q. Okay. Down at the bottom of the first page on the right side it says, "During the development of the TVT procedure different sling materials were used, such as Teflon, Gore-tex, Mersilene and Marlex."
Do you see that?
A. Yes, sir.

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Q. Is that consistent or inconsistent with your understanding of the development of TVT?
A. I think that is consistent since Dr. Ulmsten is one of the authors on this paper.
Q. It said, "All of these materials caused a significant amount of tape rejection."
Do you see that?
A. Yes.
Q. Is that consistent or inconsistent with your review of the literature?
A. That would be consistent.
Q. It says, "In a previous study Mersilene tape was found to induce a significant inflammatory reaction in paraurethral tissues with a significant increase in collagen solubility by pepsin."
Do you see that?
A. Yes.
Q. And it has a citation to Study No. 8, lead author Falconer, published in the International Urogyn Journal in 1996, correct?
A. Yes.
Q. Is that a study you've read?
A. I've seen that study before, yes.
Q. And does that study indeed show Mersilene

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tape induced a significant inflammatory reaction in the paraurethral tissues?
A. If I recall correctly, that's what the -- a paraphrasing of what the study showed.
Q. Is that consistent with your review of the study though?
A. If my -- if I recall correctly, that is a paraphrasing of what the study showed.
Q. What are the paraurethral tissues?
A. The paraurethral tissues would be the connective tissue surrounding the urethra.
Q. Just so we are clear, it is spelled p-a-r-a urethral, correct?
A. That is correct.
Q. Because I've heard you say periurethral. Is that something different or is it okay to mix paraurethral with periurethral?
A. I am not sure that there is a profound difference between para meaning lateral to and peri meaning surrounding in clinical application.
Q. And in this study they found that there was a significant inflammatory reaction induced by the Mersilene mesh compared to the minimal reaction induced by the prolene tape in these stress

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incontinent women, correct?
A. That's what this study found, yes.
Q. And they do various types of analyses, and on page 21 they report that there was practically no tissue reaction at all seen two years after TVT surgery when prolene mesh was used, citing Figure 3, correct?
A. That's what they cite, yes.
Q. And Figure 3 looks like the histology, correct?
A. It is an H&E staining of the tissue that they obtained by a punch biopsy.
Q. An H&E staining is a way of staining pathology? I call it histology.
A. It would be a histological staining, yes.
Q. Okay. And these authors, they report that -- at the very last, it says, "The reports of no tape rejections after TVT operations with prolene mesh support these experimental findings, suggesting prolene mesh to be a suitable tape material for TVT surgery," and they cite to number 14, the TVT European Experts Meeting in Cannes, 2001.
Do you see that?
A. Yes.

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Q. Were you at that meeting?
A. No, I was not.
Q. But sometime around 2001 is when you began using the TVT?
A. In 2004.
Q. Okay. All right. Fair enough.
So I want to circle back around to our discussion. Would you agree that based on the medical literature that existed in the field of stress urinary incontinence at the time -- strike that.
Would you agree based on the medical literature in the field of stress urinary incontinence treatment -- that's a bad question. Let me redo it. I'm getting tongue-tied here.
Would you agree that the medical literature -- are you with me, Doc?
A. Um-hum.
Q. Okay. Would you agree with me, Doctor, that the medical literature in the field for the intended use of stress urinary incontinence treatment supported the use of a monofilament mesh over a multifilament mesh?
MR. CARTMELL: Object to the form.
BY THE WITNESS:

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A. Specifically related to a multifilament like Mersilene, yes.
MR. SNELL: Let's mark that.
(WHEREUPON, a certain document was marked Rosenzweig Deposition Exhibit No. 6, for identification, as of 09/22/2015.)
BY MR. SNELL:
Q. Exhibit 6 has been handed to you. I'll represent to you it's out of a book, book chapter by Klinge and others. I'm sure you read about this and saw that I discussed this with Mr. Blaivas in his deposition, correct?
A. Yes.
Q. And I think you and I have touched on this paper at the time of the Perry trial but not in any real substantive context?
A. No, I think I've discussed this paper before with either yourself or one of your colleagues, or this book chapter, if you will.
Q. Book chapter, thank you.
Let's see -- then let me just cut right to the chase.
So you know Klinge is one of the

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Plaintiffs' experts, right?
A. That I'm aware of, yes.
Q. And you know Dr. Klinge has said all types of things about hernia meshes and prolapse meshes, correct?
MR. CARTMELL: Object to form.
BY THE WITNESS:
A. He has published a lot of articles about hernia mesh and prolapse mesh.
BY MR. SNELL:
Q. And when he published here with regard to the TVT, he calls it the gold standard in SUI surgery, correct?
A. As of 2009, most likely when he wrote the book chapter, having written book chapters before, it does take a significant amount of time from the time you actually put pen to paper on a book chapter until it gets published. So I would say that these probably were his opinions in maybe 2008. The paper -- the book chapter was published in 2010.
Q. Have you discussed this book chapter with Dr. Klinge?
A. I have not had any discussions Dr. Klinge.
Q. So you are discussing this was his opinion

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in 2008?
A. As I stated before, my experience from publishing book chapters, it does take about 1 or 2 years from the time you actually have written the chapter until it actually ends up in a book.
Q. But for in his case and in his book, you don't know, fair?
A. That is correct.
Q. Okay. And Dr. Klinge, he reports that -- and he cites to a paper by Meschia that looked at Amid type III mesh versus the TVT, right?
MR. CARTMELL: Where are you?
BY THE WITNESS:
A. It's the final paragraph.
A prospective control trial by Meschia showed that vaginal erosions with the Amid type III mesh for the intervaginal slingplasty was as high as 9 percent in two-year follow-up, which is significantly higher than 0 percent in the same trial.
BY MR. SNELL:
Q. Okay. And so my question for you is:
How is it that an Amid type III mesh could have so much higher rate of erosion than the TVT retropubic mesh?

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A. The --
MR. CARTMELL: Are you talking about in that study specifically?
MR. SNELL: Broader than that.
BY MR. SNELL:
Q. How can that happen?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. It would be important to look at that study specifically to be able to tell you exactly what mesh that they were looking at to determine how there would be a difference in the erosion rates between the two, how the mesh was placed, how the study was designed to be able to discuss that.
BY MR. SNELL:
Q. As you sit here today, you don't know how the mesh used in the IVS, the -- that's the product by Tyco, right?
A. Well, intravaginal slingplasty was used to describe sling procedures before the term "midurethral sling" came out.
Q. Reference 13 by Meschia, Tension-Free Vaginal Tape and Intravaginal Slingplasty For Stress Urinary Incontinence, a Multicenter Randomized Trial,

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American Journal of Obstetrics and Gynecology, 2007, volume 195, pages 1338 to 1342.
Have you read that study?
A. I have read that study, yes.
Q. Okay. And as you sit here, do you recall what type of mesh was used besides TVT?
A. Specifically sitting here today, I do not recall which mesh was used in that study.
Q. And Amid type III mesh would be what type of mesh?
A. Well, type I is micropore -- excuse me -- macropore, so according to Amid in 1997 describing a pore size greater than 75 microns, we know that from recent discussions from Klosterhalfen and Klinge's group and also a recent IUGA discussion that that classification is outdated and that the old 75 micron cutoff between type I and type II mesh, type II mesh being a pore size less than 75 microns.
Q. Can I stop you right there?
A. Yes.
Q. And say objection, move to strike.
My question was very simple --
MR. CARTMELL: Wait.
MR. SNELL: No, no, hold on, Tom.

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MR. CARTMELL: He was answering.
MR. SNELL: No.
BY MR. SNELL:
Q. My question was very simple:
What is an Amid type III mesh?
A. It would be a multifilament mesh with a combination of microporous and macroporous mesh.
Q. What Dr. Klinge reported here in 2010 in this book chapter where TVT retropubic was found to have a much lower rate of erosion than the Amid type III mesh, is that consistent or inconsistent with what Ogah reported in the Cochrane review?
A. That is not inconsistent.
Q. You say Dr. Blaivas acknowledged that TVT is the gold standard?
A. That TVT is the gold standard, if you have that part of his deposition, I would like to see that.
Q. Let me see if I can rephrase it then.
Were you aware that Dr. Blaivas agreed that TVT and the autologous pubovaginal sling were the gold standard for the treatment of stress urinary incontinence?
MR. CARTMELL: Object to the form.
BY THE WITNESS:

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A. TVT specifically or midurethral slings in general?
BY MR. SNELL:
Q. TVT.
A. Specifically?
Q. Yes.
A. If you have his deposition, I would like to see that specific quote.
Q. Well, you told me that you read his deposition. Did you recall reading that he testified to that?
A. That specific quote, which is a very specific part of the deposition, I know that you asked him questions about that, but I would like to see that specific quote before I say that's what he said. What he said in his deposition I think will be able to speak for itself.
Q. Fair enough.
MR. CARTMELL: That would be highly unusual.
BY MR. SNELL:
Q. I will agree with that. We'll move on. His testimony will stand for itself.
And just so I'm clear, you haven't had any conversations with Mr. Blaivas, have you?

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A. No, I have not.
MR. CARTMELL: If he did say that, though, he will be swiftly moved to the bench. The bench.
BY MR. SNELL:
Q. You would agree that TVT is -- I want to focus specifically on a TVT retropubic full-length sling, okay.
You would agree that the TVT retropubic device is at least as effective as the Burch colposuspension?
A. Yes.
Q. You would agree that the TVT retropubic device is at least as effective as the autologous pubovaginal sling, correct?
A. Yes.
Q. And you would agree having -- strike that.
You would agree that having that level of efficacy for a stress incontinent surgery is desirable to you as a surgeon, right?
A. What level of efficacy? The efficacy that the Burch pubovaginal sling and the midurethral sling has?
Q. Yes, because you've just agreed, right, that TVT is -- and the retropubic TVT is at least as

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effective as those two other options?
A. Yes.
Q. So my question to you is:
To you as a surgeon having that level of effectiveness is something that is very desirable, correct?
A. Yes.
Q. It's desirable not only to you as the surgeon who offers a surgery, but it's also desirable to the patients to have the potential to have a positive efficacious outcome, correct?
A. Yes, as long as the long-term adverse events are -- do not significantly change the risk/benefit ratio making the risk of the procedure outweigh the benefits of the procedure.
MR. SNELL: Let's take a break.
(WHEREUPON, a recess was had from 2:21 to 2:24 p.m.)
(WHEREUPON, a certain document was marked Rosenzweig Deposition Exhibit No. 7, for identification, as of 09/22/2015.)
BY MR. SNELL:
Q. Doctor, you've been handed Exhibit No. 7.

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And just so I understand it, this is the study by Petri that you had earlier referenced to me in one of your answers?
A. Well, there is this one and there is actually another one in the European Journal of Obstetrics and Gynecology.
Q. So which one were you referencing?
A. They both have very similar data.
Q. What are the differences in those two papers?
A. Without having the papers in front of me to compare them directly, it would be difficult to say what are the specific differences between the two.
Q. The other paper you said was published in what journal?
A. I think it's European Journal of Obstetrics and Gynecology.
Q. Was it published after or before this paper that I've handed you as Exhibit 7?
A. I think it was published after this journal.
Q. And this is the study that you referenced -- this is one of the Petri studies that you referenced?

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A. That is correct.
Q. For the proposition that more of the complications were seen between the first and the fifth year following insertion of the tape, correct?
A. I think that the other study has a better bar graph to show that. This one shows about 50 percent of the complications at 1 to 5 years.
MR. SNELL: Okay. Let's mark this one. I think I have what you are talking about, Doctor.
(WHEREUPON, a certain document was marked Rosenzweig Deposition Exhibit No. 8, for identification, as of 09/22/2015.)
BY MR. SNELL:
Q. So I've marked as Exhibit 8 another paper by lead author Petri out of the European Journal of Obstetrics and Gynecology and Reproductive Biology.
Is that the other paper that you were referencing?
A. That is correct.
Q. And what they did in both of these studies, they have similar numbers, is that they looked at complications of midurethral slings that were managed at a tertiary referral center?

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A. Yes.
Q. And one of the caveats they note in these papers, and I want to direct your attention to Exhibit No. 7, the first Petri paper we looked at?
A. Oh, yes, sir.
Q. Under the methodology, they state that, "Most of the patients were referred from other centers for the management of complications of midurethral slings. Therefore, we were unable to assess the incidence of complications due to lack of a denominator."
Do you see that?
A. Yes, sir.
Q. Is that an important methodologic caveat to this study?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. Well, when looking at complications particularly when they are referred from other institutions, what they are doing is they are highlighting the fact that they are not going to take the number of slings that they did at their institution as the denominator. So they don't -- can't say what the total number of slings were at

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these other institutions in order to get a denominator. So it is not a methodological flaw in the study. They are just acknowledging the fact that they are reporting a case series on complications.
BY MR. SNELL:
Q. Okay. Fair enough.
So what these papers do is report a case series on complications, correct?
A. That is correct.
Q. If they did know the -- strike that.
If they did know how many midurethral slings had been placed from the centers that refer cases to them, that will be -- then you could try to compute incidence?
A. Well, actually, in a paper by Marcus-Braun they did that. They looked at the incidence of their complications and their volume of surgery in the same time that they were reporting their complications and they found that 10 percent of their slings and meshes required a surgical correction of a complication.
Q. Is this paper by Braun in your -- is it cited in your report?
A. It's in the reliance list.
Q. But is it mentioned in the body of your

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report as having any particular importance?
A. Not by -- it's talking about your -- it was answering your -- it is on my reliance list, but answering your question about trying to get a denominator, that is one of the studies that actually did get a denominator and came up with the 10 percent surgical risk of a complication.
Q. But you've read other studies that reported a lower rate of a surgical reoperation with a midurethral sling, correct?
MR. CARTMELL: With a what?
MR. SNELL: With the midurethral sling.
BY MR. SNELL:
Q. Like Johnson Funk, like the paper by Whelk that just came out in JAMA Surgery, you're aware, and I think you have even listed those, correct?
A. Which study are you talking about?
Q. Johnson Funk reports a 3.7 percent rate of reoperation with TVT over a nine-year period?
A. That study has -- was recently published, yes.
Q. So, I mean, you can point to a study like you just referenced that had a 10 percent rate, but you acknowledge there are other studies that have

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lower rates of reoperation?
A. And if we want to talk about the specifics of that study, just like --
Q. Yes or no?
MR. CARTMELL: He gets to answer and then you can strike it.
Go ahead.
BY MR. SNELL:
Q. I mean, I'm looking for a yes or no.
MR. CARTMELL: No, no, let him -- go ahead, answer.
BY THE WITNESS:
A. We will see different -- there are other studies that show different rates.
BY MR. SNELL:
Q. Fair enough. Fair enough.
The SPARC device we talked about earlier, am I correct you never used that device?
A. That is correct.
Q. And you never tried the top-to-bottom TVT retropubic device?
A. That is also correct.
Q. Why didn't you ever try the SPARC?
A. The TVT retropubic was what was available

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to us.
Q. Okay. Would you agree that a potential benefit with the TVT retropubic device compared to a top-to-bottom retropubic midurethral sling is that with the bottom-to-top design you can more precisely place the tape under the midurethra?
A. No.
Q. Would you agree that you can more easily place it under the midurethra?
A. No.
Q. Okay. Have you ever placed -- done any top-to-bottom retropubic midurethral or any other type of non-autologous sling?
A. Yes.
Q. What would that have been?
A. That would be the study that we did on pubovaginal slings using Gore-tex.
Q. Okay. And you went from top-to-bottom?
A. That is correct.
Q. Was that the paper published in the 1980s?
A. '90s.
Q. '90s.
What did that study show?
A. Well, again, that was a pubovaginal sling

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that was placed specifically for recurrent severe stress urinary incontinence.
Q. Was this a study that was completed before TVT became available and on the market?
A. That is correct.
Q. Okay. Why were you using Gore-tex in that application when you already had autologous tissue arguably available to you?
A. Well, we were comparing it to fascia lata slings.
Q. I guess my question, why were you even comparing Gore-tex to fascia lata slings at that time?
A. We were looking at its utility to treat stress urinary incontinence.
Q. And what did you conclude?
A. If we could -- if you have a copy of the paper, I haven't looked at it for a while.
Q. As you sit here today, do you have a general recollection of what you concluded in that study?
A. I actually haven't seen that paper in a while. It is from I think '91 or '92, so.
Q. We'll see if we can pull it.
Should we hold off on any questions about

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that until we can get it and then we can circle back around?
A. Um-hum.
Q. You are still at the same hospital as last time when you deposed you, correct?
A. Yes, sir.
Q. Are some surgeons there still electing to use midurethral slings made of polypropylene like the TVT retropubic device?
A. Yes, sir, but fewer than before.
Q. So if I understand your opinions, in a nutshell you believe that the risk of TVT outweigh the benefit?
A. Significantly outweigh the benefits, yes.
Q. Okay. And what specifically is it about the design of the TVT retropubic device used for the application of stress urinary incontinence that you believe is defective in design?
A. I've outlined that in my report.
Q. So let's just run through and make sure I have all of the categories.
A. Okay.
Q. What page are you on just so -- I'll pull the report too.

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A. We can go to page 4 and 5 where in general my expert opinions can be summarized as following.
Q. So we have numbered paragraphs with letters A, B, C, D, E, F on page 4, carrying over G, H, I, J page 5, correct?
A. That is correct.
Q. And that's a summary of your opinions?
A. That is correct.
Q. In your opinion should Ethicon's TVT retropubic device be significantly changed or modified in its design?
MR. CARTMELL: Object to the form.
BY MR. SNELL:
Q. And if you have such an opinion, tell me how it should be changed?
A. The use of a -- and we are talking about an embodiment of something that is currently available on the market, right?
Q. No.
A. So the design should be a device that uses a partially absorbable mesh with -- such as Ultrapro which has been shown to have less stiffness, large enough pore size, light enough weight to decrease the risk of the -- long-term risks of the procedure to a

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level where the risk/benefit analysis is not significantly skewed to the risk.
Q. How many studies are there that you are aware of that analyzed the TVT retropubic device with the meshes currently in it?
A. How many studies are there?
Q. Yes, sir.
A. There are a lot.
Q. How many randomized control trials are there for the TVT retropubic device using the prolene polypropylene mesh?
A. High quality, long term?
Q. No, no, altogether.
A. Altogether, over 100.
Q. Okay. And now, so how many of those TVT retropubic device randomized control trials do you believe are high quality?
A. If you look at the assessment of the literature that's out there, the majority are of a moderate quality to low quality. They are short-term studies. They have a low number of subjects in each of the groups. They are looking mostly at efficacy. Safety is not a primary endpoint for any of the long-term studies that I have seen. They are all

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looking at safety. Many of these studies --
Q. What did you just say? I'm sorry. I missed that last?
MR. CARTMELL: He meant efficacy, I think. I think you misspoke. You said they are all looking at safety.
BY THE WITNESS:
A. Right. They are all looking at efficacy, not safety as an endpoint. Many of these studies, if not the majority of these studies, exclude -- have an exclusion criteria that makes this a highly selected group of women instead of what is the real life patient that comes into the office with a stress incontinence picture.
BY MR. SNELL:
Q. Now, I think you might have misspoke there. You said there is not safety as an endpoint in these studies, but we just looked at the Cochrane review that reported on differences of certain safety parameters, like erosion, voiding dysfunction, bladder perforation?
A. As a primary endpoint.
Q. Fair enough.
Are there any Burch studies that you are

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aware of that have safety as a primary endpoint that the study was powered on?
A. No.
Q. Are you aware of any autologous pubovaginal sling studies where safety was the primary endpoint by which the study was powered on?
A. No.
Q. Are you aware of any stress urinary incontinence studies by which safety was the variable that the primary endpoint was powered on?
A. No.
Q. And in the Cochrane reviews and various guidelines, like the AUA guidelines, the Society of Gynecologic Surgeons analyses, they do analyze complications and safety problems, correct?
MR. CARTMELL: Object to form.
BY THE WITNESS:
A. They discuss complications, yes.
BY MR. SNELL:
Q. And they actually discuss surgical treatments of some complications as well, correct?
A. Yes. There is a new classification for the IUGA-ICS classification for mesh complications.
Q. But you're also aware that, for example,

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the SGS Systematic Review and Guidelines looked at complications requiring a trip back to the operating room, for not just midurethral slings but also Burch and fascial slings too, right?

A. Yes, and in that review it found that while the safety -- excuse me -- while the subjective and objective cure rate of the Burch procedure was the same as the midurethral sling, long-term adverse events which required return to the operating room was much higher in the midurethral sling group.

Q. Okay. We'll get to that.

And I think your -- what you referenced earlier that, you know, one of the good things about Cochrane reviews and these other systematic reviews is they look at an overall, assess the quality of evidence on the endpoint that they are looking at, correct?

MR. CARTMELL: Object to the form.

BY MR. SNELL:

Q. Let me rephrase. Maybe that was a bad question.

One of the benefits to the Cochrane reviews and the other systematic reviews is to the extent they do, they analyze and comment on the

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quality of evidence of the underlying studies, right?

A. That's what they do, and Ogah and that study in 2011 found that the quality of evidence was low to moderate for the midurethral sling studies.

Q. Tell me where it shows low to moderate?

A. "The quality of evidence for the majority of trials was moderate..."

Q. What page are you on?

A. This is page 289 under Quality of Evidence. However, with a minority of low to moderate.

So if we're starting out the majority being moderate, we have a number being low to moderate, that puts it in the low-to-moderate range. Only 61 out of 7,000, which is less than 1 percent, were high quality.

"On the other hand, very few trials reported outcomes after 1 year, and the long-term efficacy and adverse effects have yet to be determined."

So they are acknowledging that there is no long-term data to -- or there isn't enough long-term data to really talk about complications.

Later on they say that, "In order to truly

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get complications studied in this review show the" --

Q. Keep going.

A. That was actually look -- "major complications such as nerve, bowel, vascular injury, hematomas, are uncommon and unlikely to be picked up in small randomized control trials. The true incidence is more likely to be determined from registries and voluntary reporting registries or data banks."

Unfortunately the registries for the TVT are short term, and as stated on such as the Austrian registry, the Dutch registry, the Scandinavian registry, they don't look at many of the complications, such as pain.

Q. The Scandinavian registry by Svenningsen in 2013 reported on a mean follow-up of more than 10 years in over 500 patients coming out of that registry, correct?

A. If you have a copy of that, we can talk about that specifically.

Q. Let me ask you this:

Are you familiar with that study?

A. I have reviewed that study.

Q. Are you aware that that study reports on

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complications at a mean follow-up of over 10 years?

A. If you have a copy of that study, we can talk about it more specifically.

Q. Do you know, though, if that study reports on complications at a mean follow-up of greater than 10 years?

A. It does talk about complications.

Q. Okay. You were just reading from the Ogah 2011 Cochrane review, correct?

A. That is correct.

Q. For the Cody 2015 Cochrane review, do you have that handy? That's Exhibit 3.

A. Okay.

Q. And here they say that they included 81 trials evaluating over 12,000 women, correct?

A. Yes.

Q. They assess the quality of evidence and the quality of most outcomes was moderate, correct?

A. Yes. Mainly due to risk of bias or imprecision. So they even acknowledge that there is a significant amount of bias in the quality of midurethral sling data.

Q. Well, they acknowledge there is a potential for bias, correct?

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A. No. They say -- not potential. For the risk of bias.
Q. Well, when they say "risk of bias", you know they are not -- what type of bias do you understand that to be?
A. Um --
Q. Hold on. Withdrawn. Let's go this way.
Have you looked at Lapitan and the other systematic Cochrane reviews for Burch and pubovaginal sling?
A. Yes.
Q. What's the overall quality of evidence that's cited by Lapitan's Cochrane review for the Burch colposuspension?
A. It would be about the same as this.
Q. Same as midurethral slings?
A. Yes.
Q. What's the overall level and rating of evidence -- strike that.
What's the overall quality of the evidence as reported in Rehman's most recent Cochrane review on the pubovaginal autologous sling?
A. I don't have that in front of me, so I can't comment exactly what they say, but I can tell

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you that there would not be a major risk of bias because there is -- there are no consultants for Burch procedures or pubovaginal slings. There are no funding for studies unless you are doing an NIH study for pubovaginal slings or Burch procedures. So someone is not working as a paid consultant, is not getting -- or being paid except for maybe an NIH grant for doing those studies.
Q. Are there other forms of bias in those non-mesh studies?
A. Well, there can be a selection bias, but that would be taken out by doing a randomized control trial. We talked about this before, retrospective studies, you can have a selection bias based on the fact that you want to show a certain outcome or your idea is that a certain outcome happens more quickly. You could have a statistical bias where you just did not have enough power to it. So there are other biases, not just financial.
Q. You can have a reporting bias, right?
A. That is correct.
Q. Particularly on complications where the surgeon maybe does not want to report all of his or her complications, correct?

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A. Well, that would be, again, if they are reporting on a new procedure that they want to get known for. I don't think that a surgeon is going to have a particular problem reporting complications unless they are, again, pioneering a new procedure.
Q. There is a bias in that some endpoints, safety endpoints may not be tracked, correct?
A. That is correct. If you don't ask about a complication, you might not find it.
Q. It says here in this 2015 Cochrane review that midurethral sling operations have been the most extensively researched surgical treatment for stress urinary incontinence in women.
Do you see that?
A. Yes.
Q. Do you agree with that?
A. I've agreed -- I stated before there are a lot of papers on midurethral slings. We've talked about before that there is a moderate quality of evidence because of bias and imprecision of the studies.
Q. But my question -- move to strike -- is very straight forward.
It says, "Midurethral sling operations

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have been the most extensively researched surgical treatment for stress urinary incontinence in women."
Do you agree with that?
A. That is what is written, yes.
Q. But do you agree with that?
A. There are a large number of studies, yes.
Q. For example, you are not aware of the Burch colposuspension having more studies assessing it as compared to the number of studies on the TVT?
A. There are not more, no.
Q. Are you aware of any ten-year studies, ten years of duration or more studies, that assess the autologous pubovaginal sling?
A. I know that you asked Dr. Blaivas that question and he was not aware of any.
Q. But are you, that's my question?
A. I don't have any more information than what he has.
Q. Okay. Are you aware of any studies that assess the autologous pubovaginal sling at a period of five years or more?
A. Yes.
Q. Besides the extended sister trial?
A. There are several others, but that's the

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main study, the extended sister.
Q. So, I think we can agree that whether it's a TVT or a Burch or an autologous pubovaginal sling, there is less data once one -- once one goes beyond one-year follow-up for all of those surgeries, correct?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. Most studies are -- would be short-term studies.
BY MR. SNELL:
Q. That's a yes?
A. Yes.
Q. For example, there is not some unknown anomaly in the literature that I'm aware of that shows that there are many more long-term studies defined as you define it, 5, 10 years or more, for autologous slings than there are studies of a duration of one year or less, correct?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. For autologous slings, no.
BY MR. SNELL:
Q. And the same would hold true for the Burch

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colposuspension?
MR. CARTMELL: Same objection.
BY MR. SNELL:
Q. There are many more studies that look at the Burch over a shorter period of time than long-term as you define long-term?
A. There are a number of studies that talk about the long-term results of Burch that we've gone over on a number of different occasions. Unlike the Schimpf 2014 SGS study, there are a few more direct comparisons, randomized control trials between Burch and TVT that were not listed in that review. But I would agree that there usually are more short-term studies than there are long-term studies.
Q. Have you done an assessment of the literature to try to figure out what is the average or expected loss to follow-up at 10 years following the index stress urinary incontinence surgery?
A. What is the expected loss to follow-up?
Q. Yes. What is the average or expected loss to follow-up at 10 years? So just to -- so we are on the same page --
A. Yes.
Q. -- I'm sure you read in Dr. Blaivas'

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deposition, we talked about a couple of studies and --
A. The Serati paper with an 8 percent loss to follow-up?
Q. Yeah, but I want to put that one to the side. So let's go to the Burch because I know you do the Burch.
You know who Stuart Stanton, Alcalay, Monga, Ash Monga are?
A. Yes.
Q. And they published out of Stanton's theories of Burch colposuspensions, correct?
A. The 10- to 20-year follow-up, yes.
Q. Perfect.
And you saw in that study that the loss to follow-up was around 60-plus percent?
A. Again, to state that with assuredness, I would need to see the paper.
(WHEREUPON, a certain document was marked Rosenzweig Deposition Exhibit No. 9, for identification, as of 09/22/2015.)
MR. CARTMELL: You are getting very duplicative.
MR. SNELL: I don't think I asked him about follow-up.

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BY MR. SNELL:
Q. Just very briefly in this study we've discussed various aspects of it, my focus though is on the loss to follow-up issue.
In here they report that a little less than one-third of the patients were followed up at long term, correct?
A. I would say that that is probably a fairly -- just adding up the numbers of the ones that didn't reply, change their address or had died, that number seems to be accurate.
Q. Okay. So obviously there can be significant loss to follow-up in ten years and on because of a variety of reasons?
A. That is correct.
Q. And that's true whether it's a midurethral sling like the TVT or the Burch colposuspension that you like, correct?
A. That is correct.
Q. So circling back around, my question to you was:
Had you formulated an opinion or did you have an opinion on what is the average or expected rate of loss to follow-up at 10 years and beyond?

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MR. CARTMELL: Object to the form.
BY MR. SNELL:
Q. And I'm trying to make it easy. I mean, if you have it, fine. If you don't have the opinion, fine, I'll move on.
A. I don't have an opinion about that.
Q. Okay. And you can put that to the side.
A. Okay.
(WHEREUPON, a certain document was marked Rosenzweig Deposition Exhibit No. 10, for identification, as of 09/22/2015.)
BY MR. SNELL:
Q. Exhibit 10, Doctor, is the paper we were going to come back to where you and some others looked at Gore-tex versus autologous fascia lata, correct?
A. That is correct.
Q. And what did this study show?
A. The conclusions of the study was that Gore-tex patches were more advantageous than fascia lata because it does not require a second surgery but may be associated with more obstructive complications.
Q. When you said "it does not require a second surgery," what were you talking about there?

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A. An incision to harvest the fascia lata.
Q. So as between TVT and autologous pubovaginal sling, that's a benefit for TVT that it does not require the second surgery to harvest, correct?
A. Specifically using the fascia lata.
Q. That's, yes, specifically using the fascia lata?
A. Yes. You don't have to use, you know, exclusively fascia lata. You can use rectus fascia.
Q. Okay. And a benefit of TVT is that you don't have to harvest rectus fascia either, correct?
A. You don't have to harvest rectus fascia.
Q. Is that a yes?
A. Well, the way I do it you're making your incision at the level of the rectus fascia. So you get to the rectus fascia, you've used that to fashion your pubovaginal sling.
Q. Oh, so I understand, I think. Maybe I'm wrong though.
So the way you do it, you actually incise the rectus fascia, but you don't completely harvest it and take it out? I'm confused.
A. No, you leave -- you -- you harvest -- you

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make an incision through the skin. You get down into the rectus fascia. You take your piece of fascia lata off of that. So it's just extending the fascial incision by the extra centimeter in order to get the rectus fascia and then you will bring that down underneath the urethra and attach it to the rectus fascia at the level of the midline. So you are not making a separate incision because you are going through the rectus fascia to accomplish your -- your access into the space of Retzius.
Q. You are taking the -- normally the rectus fascia is in the same plane, is that right?
A. Yes.
Q. And then what you do is you excise or cut it and you bring it down below the midurethra?
A. Yes.
Q. But you don't totally detach it at the ends?
A. No, you do, but you bring it together. You attach it to the underlying rectus fascia of the midline. Maybe you need to go to medical school.
Q. I think I do.
And so in this study you all found that Gore-tex, I guess the efficacy in Gore-tex was

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comparable to the fascia sling?
A. Yes.
Q. What about safety?
A. If we look at some of the complications associated with Gore-tex, there was more obstruction associated with the Gore-tex sling.
Q. Did you continue to use Gore-tex as a sling after this study?
A. For a short period of time afterwards.
Q. What was it that made you stop using Gore-tex?
A. I think that some of the long-term complications from Gore-tex I did not find to be acceptable.
Q. What were those?
A. You can -- Gore-tex does not integrate very well. I think that most of us, you know, stopped using Gore-tex for the use in the pelvis in the early to mid-'90s based on experience with it.
Q. Gore-tex is one of those type III meshes?
A. It is a type IV.
Q. Type IV.
A. There are virtually no pores in Gore-tex.
Q. Now, you had earlier said that you

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believed that the design of TVT should have used a partially absorbable mesh like Ultrapro, correct?
A. That's an embodiment, yes.
Q. And what clinical studies in women for the application of stress incontinence, if any, are you relying on for that statement?
A. We have the Okulu study which used Ultrapro and showed to have a higher success rate, lower complication rate, than a stiffer, smaller pore, heavier weight mesh. You -- the -- work from the Moalli group, there were multiple studies on mesh stiffness showing the complications associated with a stiffer mesh. There are more complications associated with a heavier weight mesh. There are more complications associated with a smaller pore mesh. So, if you design a mesh that is lighter weight, larger pore, less stiff, smaller filament size, you will have fewer complications and have a better risk/benefit ratio.
Q. How many randomized control trials are you aware of that have evaluated Ultrapro and the intended use of stress urinary incontinence?
A. There is the Okulu study.
Q. So one study?

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A. That is correct.
Q. And that's the Okulu study we discussed earlier today?
A. That is correct.
Q. That was in 2003?
A. Yes.
Q. So for your statement that the lighter weight, larger pore mesh should have been used, you can cite to a single clinical study in women with the application of stress urinary incontinence, the Okulu study?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. Well, there are other studies showing the why you would move to a -- in a pelvic floor application to a larger pore, lighter weight, smaller filament, less stiff mesh.
BY MR. SNELL:
Q. But the larger pore, lighter weight, less stiff theory that you are talking about has only been tested in one study you can point me to for the application of stress urinary incontinence?
MR. CARTMELL: Object to the form.
BY MR. SNELL:

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Q. Correct?
A. Specifically for stress urinary incontinence, yes, but for -- but to show why that is, there are multiple studies that show why it's advantageous in the pelvic floor to have a larger pore, lighter weight, less stiff mesh because of processes that lead to cell death, that lead to smooth muscle dysfunction, that lead to more erosions, that lead to more complications.
Q. The Moalli papers you are referring to are not in women who received Ultrapro and who received Ultrapro for stress urinary incontinence and were followed over one or more years, correct?
A. The multiple studies by the Moalli group that looks at the stiffness of mesh and the consequence of stiffness of mesh are in an animal model. There is basic science research that shows the difference between the stiffness of mesh. There are multiple other clinical studies that show the decrease in complications associated with a lighter weight, larger pore mesh compared to a medium weight, smaller pore mesh.
Q. And just so I'm clear, all of the Moalli papers you cited are animal model papers?

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A. That is correct, the half a dozen or more are animal model papers, yes.
Q. Chimpanzees, rabbits, any specific species, monkeys?
A. No. They are upper level primates.
Q. In the hierarchy of evidence, where do animal studies fit in compared to prospective randomized control trials in women or prospective observational cohorts or retrospective or prospective epidemiologic observational studies or case series in women?
A. If you are looking at a risk and you are trying to answer what is the mechanism behind the risk, then using an animal model is the most appropriate way to find that.
Q. There can be differences in findings for animals across the species, correct?
A. Yes, but the use of an upper level primate would be the closest to looking at the basic science in a female.
Q. What is the basis for that statement?
A. It's -- they are the closest species to us as far as our genetic makeup, our bipedal mobility, so that if you are -- you know, if you are going to use

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an animal model, using an upper level primate would be the closest model that we have to using it in humans.
Q. You mentioned other studies utilizing the lighter weight, larger pore mesh. I take it you were referring to prolapse or hernia studies?
A. Well, all of the slings that -- midurethral slings that are currently on the market, just like the SPARC that we were talking about before, SPARC just like the TVT retropubic is a heavy weight, small pore stiff mesh. So, therefore, because there is a slight difference in the erosion rate between SPARC and TVT, it is still a heavy weight, stiff, small-pore mesh just like the TVT and, therefore, will have the same defect of a heavy weight, small pore, stiff mesh as the TVT.
Q. Now, I thought you have testified under oath before that the laser cut form of cutting the TVT mesh leads to a stiffer mesh?
A. No. It in- -- well, it does increase the stiffness of an already stiff heavyweight mesh.
Q. And you've also testified that a laser cut TVT mesh has a higher risk of exposure, correct?
A. The laser cut TVT compared to the mechanical cut TVT does have a higher rate of

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exposure.
Q. And you're familiar with prolapse studies using Ultrapro mesh that found exposure rates of upwards of 14 to 15 percent, correct?
A. When Ultrapro --
Q. That's a yes or no. Are you aware of those studies or no?
MR. CARTMELL: Let him answer and then you can --
MR. SNELL: No, no, no. I'm going to ask because this is going to the judge.
BY MR. SNELL:
Q. I'm going to ask you for a yes or no and then you can explain all you want to. I'm just saying, you're aware?
A. I'm aware of a Milani study that showed a 10 percent risk of erosion with Ultrapro.
Q. Are you aware that when they reported the median term outcomes that the rate of exposure was greater than 14 percent in that same cohort using Ultrapro for a different application?
A. That is correct.
Q. Okay.
A. However, when head-to-head Ultrapro with

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GYNEMESH PS, there were half of the erosions with Ultrapro.
MR. SNELL: Let's take a break. I think we are moving things along here.
(WHEREUPON, a recess was had from 3:15 to 3:33 p.m.)
BY THE WITNESS:
A. Before we get started, I think I might not have completely understood your question about the design and, you know, obviously what I would design out are the things that I've outlined in my report, the roping, fraying, curling, degradation, contraction of the mesh.
Now, obviously the best way to do that is with the alternatives that I've been describing, the Burch procedure, the pubovaginal sling procedure. If it was a -- I mean, I used Ultrapro as an example since that is an example that is on the market. Obviously in order to justify the use of a polypropylene-based product like Ultrapro, there would have to be a significant amount of research to be able to make sure that the amount of polypropylene that's leftover in Ultrapro, it is large -- a lighter weight, larger pore, smaller filament size is "biocompatible"

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with tissue.
If you look at a single suture of polypropylene, that is probably below the minimal amount of polypropylene that is biocompatible with the body, just like when you look at flu vaccines, a flu vaccine has heavy metals in it, such as mercury and others. There is a minimal amount of -- of things like heavy metals and other toxic substances that is still biocompatible, even though at higher levels it becomes bioincompatible.
And, so, therefore, there would need to be a significant amount of research to look at the -- whether the amount of polypropylene in Ultrapro is still at the level of biocompatibility. The research does seem to show that it is, as we've talked about before in other depositions, but that would also need to have, you know, a significant amount of research to be able to say if that is the case.
BY MR. SNELL:
Q. Well, you and I both know from looking at the literature that there can be exposures and dyspareunia with the Ultrapro mesh followed in women implanted with that mesh for pelvic floor indications, specifically pelvic organ prolapse, right?

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A. That is correct.
Q. And what is the minimum amount of prolene polypropylene that is biocompatible?
A. Well, again, we know that heavyweight, small pore, large filament mesh that curls, degrades, ropes, frays is not biocompatible. A single suture of polypropylene is biocompatible. So there is in between that a level of polypropylene that would be minimal enough to be biocompatible.
Q. So my question is:
What is the minimal amount of prolene polypropylene that is biocompatible? And if you know that, what is the methodology by which you have -- you can identify for me that minimum amount?
A. Well, the methodology would be the risk/benefit analysis that shows the least amount of risk for the benefit. From what I see with Ultrapro, the studies that look at the stiffness of Ultrapro, that look at the percentage of complications being half of that of the next category of weight would show me that Ultrapro comports with that biocompatibility.
Q. So the Ultrapro mesh regardless of its size to you is biocompatible, correct?
A. The -- irregardless of the size?

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Q. Yes.
A. Of the amount of mesh?
Q. Yes.
MR. CARTMELL: Objection.
BY THE WITNESS:
A. Well, we are talking about using it as a sling.
BY MR. SNELL:
Q. No, no, no. My question was:
What is the minimum amount of prolene polypropylene that is biocompatible?
A. As a sling.
Q. No, no.
I want to know what's the minimum amount of prolene polypropylene that is biocompatible in the body?
MR. CARTMELL: Well, he is testifying about slings.
MR. SNELL: Hold on. Don't do a speaking objection.
BY MR. SNELL:
Q. Because I'm asking that because you said two things. You said we have essentially two ends of the spectrum. A single polypropylene suture, yes, I

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believe that's biocompatible. The mesh, and you keep talking about heavyweight, large pore, small pore mesh, no, that's not. I want to know where is it that -- what is the minimum amount of prolene polypropylene that is biocompatible?
A. For a sling?
Q. No. This is in the body in general because you've now raised two different spectrum. Because the sling doesn't use the prolene suture by itself, right?
A. That is correct. You have a --
Q. And then for the other end --
A. -- you have hundreds of yards of polypropylene.
Q. The other end of the spectrum, you were referring to prolapse or hernia mesh or some other application, right?
A. I was looking at that as a sling application.
Q. Okay. Fine.
So between the spectrum then, can you tell me, what is the minimum amount of prolene polypropylene that's biocompatible?
A. Somewhere at the level of Ultrapro or less

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as a sling.
Q. And so what clinical studies in women allow you to make that statement for the application of stress incontinence besides the Okulu that we've already talked about?
A. And all of the other research about Ultrapro as a -- being implanted in both the female pelvis and in animal models.
Q. There is no randomized control trials comparing TVT to Ultrapro in the application of TVT's treatment of stress incontinence, right?
A. That is correct.
Q. You've never used Ultrapro as a sling to treat stress incontinence?
A. That is correct.
Q. There are no long-term studies utilizing Ultrapro in women to treat stress urinary incontinence, correct?
A. Long-term, the Okulu study I think it was three years.
Q. So I would be correct that there are no long-term studies utilizing Ultrapro in the treatment of stress urinary incontinence, correct?
A. That is correct.

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Q. In the Okulu paper, that single paper tested Ultrapro in limited numbers of women, correct? We looked at the paper. The numbers are what they are, right?
A. That is correct.
Q. Certainly you would agree with me that TVT has been studied in hundreds of times more women than Ultrapro for the application of stress incontinence, correct?
A. That is correct.
Q. And you, therefore, do not know the five-year-plus complication rates with Ultrapro when utilized in the application of stress urinary incontinence treatment, correct?
A. That is correct. But that is why I say that the safest design is using the Burch procedure which has been shown to have the same efficacy of the midurethral sling and lower long-term adverse events, such as returning to the operating room for erosion, returning to the operating room for obstruction, returning to the operating room for pain, and returning to the operating room for overactive bladders.
Q. We can agree that the Burch is not a

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design, it is a surgery, correct?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. It is a surgical procedure to treat stress urinary incontinence.
BY MR. SNELL:
Q. The Burch is not a medical device, right?
A. It is not a medical device.
Q. The autologous pubovaginal sling is not a medical device, correct?
A. If you use a collagen-based pubovaginal sling, that would be a medical device.
Q. No. I said the autologous?
A. Autologous, that is not a medical device.
Q. Right. That strips the woman's own tissue out and uses that, correct?
A. It uses a piece of the patient's own tissue.
Q. Do you have any plans of testing or doing a well-designed, well-carried out randomized control trial assessing Ultrapro for the application of stress urinary incontinence treatment in women?
A. I have not filed a grant application for that, nor an IRB approval for that.

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Q. Ultrapro uses the prolene polypropylene, that specific compound that's also used in TVT, right?
A. That is correct.
Q. And one of your opinions you've told me before is you believe prolene polypropylene degrades, correct?
A. Yes.
Q. And actually part of what you cite on as relief for that opinion are suture studies involving prolene sutures, right?
A. Yes.
Q. At what rate does Ultrapro degrade?
A. Because it is lighter weight, larger pore, less stiff mesh, it's going to degrade less than a heavyweight thicker filament mesh.
Q. And what studies in women use -- assessing stress incontinence show that?
A. Assessing stress incontinence?
Q. Yes.
A. There aren't any.
Q. What studies in women show that Ultrapro degrades less than the prolene mesh in TVT?
A. What studies show that Ultrapro degrades less than the heavyweight mesh in TVT?

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Q. What study -- yeah, what studies in women show that the Ultrapro mesh as you've stated degrades less than the mesh in TVT?
A. The Clave study shows that heavyweight mesh has a higher degree of degradation than lighter weight mesh. The heavyweight mesh would be the mesh used in TVT, the lighter weight mesh would be mesh analogous to Ultrapro.
Q. But there was degradation even in the lighter weight Ultrapro arm in Clave, right?
A. That is correct.
Q. And there was degradation, as you have opined, in the arm that would have had the TVT mesh, correct?
A. That is correct.
Q. And you and I have discussed this, but overall about 1/3 of the polypropylene cohort had those pictures of surface cracking, right?
A. No. Over half of the -- or approximately half of the heavyweight mesh are degradation and only about 25 percent of the lighter weight mesh are degradation.
Q. How was it that some of the lighter weight mesh still degraded?

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A. How is it?
Q. Yeah.
A. Well, we know from the suture studies that mesh will continue to degrade.
Q. So even the lighter weight mesh degrades in your opinion?
A. Yes.
Q. And that's a defect in the lighter weight mesh too, correct?
A. Yes.
Q. And in your opinion, let me ask you this, explain to me how the Burch colposuspension is an alternative design to TVT? What is it about TVT -- strike that. Let me just back up and just ask you this simple question.
Did I hear you correct to say that the Burch colposuspension is an alternative design to the TVT retropubic device for the treatment of stress urinary incontinence?
A. It is not a device as we said. It is an alternative.
Q. It is an alternative surgical option that surgeons can turn to if they so choose, correct?
A. And it's been shown to have the same

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efficacy but less long-term adverse events.
Q. Is the answer to my question yes?
A. It is a surgical device. It is a surgical procedure, yes.
Q. Do any of the gynecologic surgeons at Rush use Ultrapro to treat stress urinary incontinence?
A. No.
Q. Did I understand you to say that the autologous pubovaginal sling is an alternative design to the retropubic TVT for the treatment of stress urinary incontinence?
A. It is an alternative surgical procedure.
Q. And it is one that surgeons can freely employ if they so choose, correct?
A. That is correct.
Q. Just like the Burch, correct?
A. That is correct.
Q. And whether or not a surgeon can do a Burch procedure or an autologous fascial sling is ultimately determined between the surgeon, his or her patient, and the facility where it would be carried out, correct?
A. I don't think that the facility where it is going to be carried out is part of that discussion.

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I don't understand what you mean by the facility where it is being carried out.
Q. Well, wouldn't the surgeon have to be credentialed to do the Burch to do it at that hospital? That is to say, I couldn't walk into Rush and do a Burch because I'm not credentialed, right?
A. Right, but that's more of the surgeon than the facility. That's why I didn't understand the facility.
Q. So when I said "facility", I meant as long as the surgeon is credentialed to do that -- whatever type of stress incontinent surgery he decides to proceed with, that's between him and the facility, the hospital?
A. That is correct.
Q. Are you aware of whether some gynecologists are no longer even trained on the Burch in their residency?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. I know my institution, my residents are trained on the Burch procedure.
BY MR. SNELL:
Q. Are you aware of other residencies where

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they are not trained on the Burch procedure?
A. Not that I'm aware of.
Q. Are you aware of any other residencies -- strike that.
Are your residents trained on the autologous fascial sling?
A. Yes.
Q. Are you aware of any other residencies where the residents are not trained on the autologous fascial sling?
A. Not that I'm aware of.
Q. Okay. Have you decided to sit for the subspecialty Female Pelvic Medicine and Reconstructive Surgery Boards?
A. No, I have not.
Q. Have you purchased or looked at any of the course study materials for that program?
A. No, I have not.
Q. Do you have an understanding as to whether or not knowledge of midurethral slings is tested in that subspecialty certification?
A. More likely than not it would be.
Q. Do you believe Ultrapro is cytotoxic?
A. Yes. However, as I talked about before,

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there -- just like the mercury in flu vaccines, there would be a minimal level of cytotoxicity which would not have clinical significance.

Q. And what methodology allows you to make that statement?

A. Well, the same methodology where it is determined that there is a minimal concentration of mercury, of arsenic, of any toxic compound that the body can be exposed to.

Q. So where has Ultrapro been tested and it has determined what particular concentration of Ultrapro will lead to cytotoxicity?

A. Well, we know that when TVT was tested back in the late '90s, it was found to be moderately to severely cytotoxic, particularly in the Scotland study, so that that would be the basis of cytotoxicity.

Q. What Scotland study are you referring to?

A. The Scotland cytotoxicity study that is referenced in my report.

Q. Help me out here. So are you talking about the petri dish studies that were made up and were reported to the FDA in connection with the TVT 510(k)?

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A. Yes.

Q. My question for you is:

Have you reviewed cytotoxicity results for Ultrapro mesh?

A. Specifically for Ultrapro mesh?

Q. Yes.

A. Not that I've seen.

Q. When attempting to use Ultrapro in the design of TVT and the sling to treat stress urinary incontinence, you are aware that the Monocryl in the Ultrapro sticks to the sheaths?

MR. CARTMELL: Object to the form.

BY THE WITNESS:

A. Stick to?

BY MR. SNELL:

Q. The sheath.

A. Which sheath?

Q. The sheath that goes over top of the TVT.

A. If the polypropylene sticks to the sheath in Ultrapro, it is going to stick to the sheath in TVT too.

Q. Let me ask you this question then.

Do you know whether or not when you put Ultrapro in the configuration of a sling and you put a

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sheath on it, like one is utilized with TVT, and you sterilize it, does the Monocryl stick to the sheath?

A. I have not seen any indication that that is the case.

Q. Would it be important to you -- I'm going to ask you a hypothetical.

Hypothetically assume for me that the Monocryl sticks to the sheath and when the sheath is pulled off deploying the sling, the Monocryl comes apart and it unravels and interferes with the integrity of the sling.

Would that be an impairment in the utility of the sling potentially?

MR. CARTMELL: Object to the form.

BY THE WITNESS:

A. Then another delayed absorbable material like PDS could be used and then more likely than not it wouldn't stick to the sheath.

MR. SNELL: Move to strike.

Can you read back my question?

(WHEREUPON, the record was read by the reporter as requested.)

BY THE WITNESS:

A. And I said, yes, and, therefore, a --

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MR. SNELL: Hold on. Did he say yes in the beginning?

(WHEREUPON, the record was read by the reporter as requested.)

BY MR. SNELL:

Q. So you didn't say yes.

A. I apologize. I meant to say yes and then answer with the rest of the answer that I gave.

Q. Okay. How many randomized trials -- strike that.

How many randomized control trials are there assessing PDS in the application of a stress urinary incontinent sling?

A. It has not been studied.

Q. Would you agree with me that laser cut is not safer than mechanically cut mesh?

A. Laser cut mesh has a different set of harms that it causes. It makes the mesh stiffer, the mechanical cut mesh. The mechanical cut mesh ropes, frays, curls, twists. There is particle loss associated with it. The mechanical cut mesh decreases the roping, fraying and curling but makes the mesh stiffer.

Q. And you've told me before under oath and

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you testified actually to a California jury that a stiffer laser cut mesh can lead to more retention.
Do you recall that?
A. If that's what I stated, yes.
Q. That's an opinion you hold, correct?
A. If that's what I stated, yes.
Q. Can you say to a reasonable degree of medical certainty that laser cut mesh is safer than mechanically cut for the application of stress urinary incontinence treatment?
A. Mechanical cut mesh ropes, frays, curls, has particle loss associated with it. It twists. It has sharp edges. Laser cut mesh is stiffer than mechanical cut mesh but it also contracts, degrades, undergoes a chronic foreign body reaction, chronic inflammation. They both have different harms that are caused by the cutting process.
MR. SNELL: I'm going to have to move to strike.
Can you read back my question?
BY MR. SNELL:
Q. And if you can answer it yes or no and then explain.
(WHEREUPON, the record was read by the reporter as requested.)

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BY THE WITNESS:
A. It is safer because it does not rope, fray, curl and have particle loss.
BY MR. SNELL:
Q. And what's your methodology for that statement?
A. The methodology for that statement is my clinical experience with mechanical cut mesh, the materials that I've reviewed in this litigation, internal documents, the documents that discuss the decrease in the roping, fraying, curling associated with laser cut mesh that was documented in the internal documents that I reviewed.
Q. What clinical studies in women for the application of stress urinary incontinence show that laser cut mesh is safer than mechanically cut mesh?
A. As far as roping, fraying, curling?
Q. So maybe my question wasn't clear.
What clinical studies in women for the application of stress urinary incontinence show that the laser cut mesh is safer than the mechanically cut mesh in TVT?
A. As it relates to roping, fraying, curling and particle loss?

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Q. At all. Because roping, fraying, curling, particle loss are not complications, are they?
A. No. They cause erosion, pain and dyspareunia.
Q. Right. And you already told me before laser cut mesh has a higher risk of erosion than mechanical cut mesh, right?
A. Because it is stiffer, yes.
Q. Right. So that leaves pain and dyspareunia, correct?
MR. CARTMELL: Object to form.
BY THE WITNESS:
A. Well, mechanical cut mesh causes erosion for a different reason than laser cut mesh.
BY MR. SNELL:
Q. Right. So what studies in women show that the mechanical cut mesh has a higher rate of erosion than the laser cut?
A. When laser cut is compared to the mechanical cut mesh in the Hinoul, H-i-n-o-u-l, TVT study, there was a higher rate of erosion than the laser cut mesh.
Q. So my question was:
What studies in women for the stress

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incontinence application showed that mechanically cut mesh leads to more erosions than laser cut mesh?
A. The only study that directly compared laser cut mesh with mechanical cut mesh showed a higher rate of erosion in the laser cut mesh.
Q. Okay. What clinical studies in women for the application of stress incontinence show a statistically significant higher rate of pain seen with the mechanically cut mesh compared to the laser cut TVT mesh?
MR. CARTMELL: Can you restate that? I apologize.
MR. SNELL: I'm going to have her read it back because I think it's a good question.
(WHEREUPON, the record was read by the reporter as requested.)
BY THE WITNESS:
A. Besides the one study that I referenced, there are no known direct comparisons between laser cut mesh and mechanical cut mesh that looks at safety outcomes.
BY MR. SNELL:
Q. What one study are you referencing?
A. The Hinoul study in the Journal of

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Urology.
Q. The Hinoul study did not show mechanically cut TVT mesh had a higher rate of pain than the laser cut mesh, correct?
A. Well, you were looking at an obturator sling versus a mini-sling, and so there would be -- there was higher pain associated with the obturator sling, which was the mechanical cut mesh.
Q. Let me restate.
The Hinoul study that you referenced as the only study that you are aware of is a transobturator versus TVT-Secur mini-sling randomized trial, right?
A. That is correct.
Q. Okay. So for the application of the TVT retropubic device, am I correct that you are not aware of any randomized control trials in women looking at stress urinary incontinence that show a statistically significant higher rate of pain for the mechanically cut TVT compared to a laser cut TVT?
A. That is correct, and the reason for that is it was not studied in women. Doctors were told that mechanical cut mesh and laser cut mesh were the same. There were no clinical studies to show whether

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or not mechanical cut mesh versus laser cut mesh was safer in a randomized control trial.
Q. Have you seen in any of the professional organization statements and guidelines and meta-analyses that they have reported that mechanical cut TVT mesh has statistically significant higher rates of pain than the laser cut TVT mesh?
A. As we know from the internal documents, most doctors don't know whether they are getting mechanical cut mesh or laser cut mesh. Most doctors don't even know that there is a difference between mechanical -- that there is a mechanical cut mesh versus laser cut mesh.
MR. SNELL: Move to strike his answer to my question.
BY MR. SNELL:
Q. Is the answer to my question no?
MR. CARTMELL: What was your question again?
MR. SNELL: You have to read it back. I'm sorry, Madam Court Reporter.
(WHEREUPON, the record was read by the reporter as requested.)
MR. CARTMELL: Object to the form. I think you are insinuating that's in the statements and that's

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nowhere to be found in any statement.
BY MR. SNELL:
Q. My question is:
Have you seen that, whether that's in those statements?
A. No, for the reason that I have stated.
Q. Are you aware of any randomized control trials in women that report that the mechanically cut TVT retropubic mesh has a statistically significant higher rate of dyspareunia compared to laser cut TVT retropubic mesh?
A. No, for the reasons that I stated earlier.
Q. Are you aware of any clinical studies suggesting an increase rate of pain with sex attributable to laser cut mesh?
A. Yes.
Q. Which studies are those?
A. Those are the Neumann studies.
Q. What does that study report with regard to the laser cut mesh?
A. It's a TVT-Secur, TVT-Obturator study that showed 9 percent dyspareunia with laser cut mesh. Secur compared to the TVT and the Neumann states that the laser cutting leading to stiffness of the mesh

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increases dyspareunia.
Q. So there was a 9 percent dyspareunia rate with the laser cut mesh?
A. That is correct.
Q. And that would have been the Secur, the TVT-Secur arm?
A. That is correct.
Q. The TVT-O arm was mechanical cut in the Neumann paper?
A. That we don't know.
Q. What was the rate of dyspareunia with the TVT-O arm in Neumann?
A. To state that with assuredness, I would need it.
Q. Does 0 percent sound right?
A. That is correct.
Q. Have you cited the Neumann study in laser cut cases for the proposition that laser cut mesh has a higher risk of dyspareunia than mechanical cut?
A. That those studies are on my reliance list.
MR. SNELL: Move to strike.
BY MR. SNELL:
Q. Have you cited the Neumann study for the

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proposition that laser cut mesh has a higher risk of dyspareunia compared to mechanical cut?
A. In what?
Q. In any reports or testimony or litigation you've given.
A. I have not authored a Secur report, nor have I been given a deposition.
Q. So you've never cited to the Neumann paper as a source for an opinion that laser cut mesh has a higher risk of dyspareunia than mechanical cut?
A. Not that I recall.
MR. SNELL: Okay. Let's take another break.
(WHEREUPON, a recess was had from 4:08 to 4:12 p.m.)
BY MR. SNELL:
Q. Doctor, you're aware that here in the United States more surgeons utilize the TVT mechanically cut mesh than the laser cut mesh, right?
A. Yes.
Q. And you know that TVT retropubic device that we've been talking about here today has been studied in recurrent stress incontinence series of women?
A. Yes.

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Q. You are aware that the TVT retropubic device has been studied in a series of patients who have what's termed mixed incontinence?
A. Yes.
Q. And you're aware that in those -- in various studies that have analyzed TVT retropubic's use in patients with mixed incontinence, a significant percentage of those patients' mixed incontinence -- strike that. Let me rephrase it.
You are aware that a significant percentage of the women who have mixed incontinence after implantation with the TVT retropubic have improvement in their urge symptoms?
A. And what do you mean by "significant"?
Q. Statistically significant improvement based on different scales and questionnaire assessments that are standard in your field.
A. There are women that their urgency symptoms get better, there are women whose urgency symptoms get worse and there are women whose urgency symptoms stay the same.
Q. It is a utility of TVT that some of those urgency symptoms get better in women, correct?
MR. CARTMELL: Object to the form.

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BY THE WITNESS:
A. That is true for any surgical procedure for stress urinary incontinence, a certain percentage of women's overactive bladder gets better, a certain percentage gets worse and a certain percentage stays the same.
BY MR. SNELL:
Q. And TVT has been studied in patients who have ISD?
A. That is correct.
Q. And TVT has been studied in patients who are overweight or obese, correct?
A. That is correct.
Q. And to your knowledge, Ultrapro, PDS, Vypro, none of those lighter weight, larger pore meshes have been studied as much as the TVT retropubic mesh in any of those cohorts, retropubic -- I'm sorry -- recurrent stress incontinence, mixed incontinence, ISD or the obese and overweight, correct?
A. That is correct.
Q. You earlier mentioned Schimpf, so I just want to mark that.
(WHEREUPON, a certain document was

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marked Rosenzweig Deposition Exhibit No. 11, for identification, as of 09/22/2015.)
BY MR. SNELL:
Q. So this a systematic review and recommendations along with recommendations by the Society of Gynecologic Surgeons?
A. That is correct.
Q. This is a paper you've read before?
A. Yes.
Q. Was there any of the surgeons out of the Chicago area involved in this paper that you recognize?
A. It does not look so.
Q. Fair enough.
And as we were earlier saying, the paper -- it actually compared the midurethral sling, particularly the TVT retropubic, to the Burch and the autologous fascial sling, correct?
A. That is correct.
Q. And for the Burch, the midurethral sling and the Burch essentially came out even on efficacy, right?
A. Yes. It states for the midurethral sling

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versus Burch, it showed no significant difference between the objective cure rates.
Q. And if you look at Table 1, it's got all of these different randomized controlled trials in there. You can see that the original retropubic TVT midurethral sling is the most studied of all of the procedures, correct?
A. In the comparison?
Q. In all of the comparisons, right?
A. That is the one that is used the most in the comparisons, yes.
Q. And that's consistent with your overall analysis of the literature, that the original retropubic TVT midurethral sling has been studied against other surgeries more than any other potential type of mesh for the application of stress incontinence?
A. Yes.
Q. And as you I think mentioned earlier, there was equal efficacy between the Burch and the midurethral sling, correct?
A. Yes.
Q. And they said the decision should balance on potential adverse events and concomitant surgeries

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as to whether a doctor may choose to proceed with a midurethral sling like the TVT or with the Burch, correct?
A. That is correct.
Q. And then for the women considering the pubovaginal sling versus the midurethral sling, they say the metaanalysis of subjective cure favored the midurethral sling, correct?
A. Over the pubovaginal sling?
Q. Yes, sir.
A. Yes.
Q. And so they recommended midurethral sling, correct?
A. Yes.
Q. And in that analysis as well, the original TVT retropubic device we've been talking about was the most assessed device, correct?
A. Correct.
Q. For comparison of the pubovaginal sling like Dr. Blaivas likes to do primarily and the Burch that you look as a primary procedure, they reported that slings were favored by both subjective and objective cure?
A. That's what they state, yes.

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Q. And so they recommended pubovaginal slings to maximize cure outcomes, correct?
A. And if you looked at --
Q. First can you just say yes or no?
A. Yes.
MR. CARTMELL: No, just let him answer. You know, I deal with this constantly with this guys, okay. Your witnesses, corporate witnesses, 25 of them I've taken. They never say yes first, okay. They go on forever. And I get told repeatedly, you have to let him answer the question, okay. He doesn't have to do what you want him to do. You can move to strike it, okay.
MR. SNELL: We are wasting time if I have to move to strike it.
MR. CARTMELL: No, we are not. Don't interrupt him.
All right. Go ahead and answer the question.
MR. SNELL: How about this, quick putting speaking objections on the record that you know are blatantly and boldly improper, Tom. I give you a lot of leeway. I'm just asking for a yes and I'm more than happy for him to explain whatever he wants.

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MR. CARTMELL: You just interrupted him, and you have multiple times. All I want you to do is let him answer and then move to strike if you feel like you need to.
MR. SNELL: That's fine. And don't tell me about time, because if you want to give me these long-winded answers and then try to come around at the end, that's fine, we are going to be moving to strike, but I think it was a simple question.
MR. CARTMELL: Go ahead, answer the question.
MR. SNELL: Madam Court Reporter, can you read back the question so the doctor has it fresh in his mind.
(WHEREUPON, the record was read by the reporter as requested.)
BY THE WITNESS:
A. Yes. However, two of the four studies that were used were not autologous fascial sling studies. They were Gore-tex pubovaginal slings and one was a dura mater pubovaginal sling.
BY MR. SNELL:
Q. When you read this systematic review, I take it you didn't go and alter your decision to stick with the Burch as your primary stress incontinence

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operation, right?
A. No, but this I did agree with why pubovaginal sling as a rescue operation to treat severe stress -- severe stress urinary incontinence.
Q. Do you think by not following this guideline and going to pubovaginal autologous -- strike that.
Do you recommend -- strike that.
Do you believe that by not following the guideline of utilizing the pubovaginal sling first above Burch that you are practicing contrary to the standard of care in your field?
MR. CARTMELL: Object to the form. It misstates the document.
BY THE WITNESS:
A. Again, the document says that compared to midurethral slings, Burch has the same efficacy.
BY MR. SNELL:
Q. I'm not talking about that. I'm talking about pubovaginal and Burch.
A. I use the pubovaginal sling and I use that in patients who need a greater degree of efficacy.
Q. So you think you use the pubovaginal sling consistent with these guidelines?

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A. It is a procedure that gives you better efficacy in the hands of patients that have recurrence of stress urinary incontinence.
Q. So you don't read this Schimpf metaanalysis to recommend pubovaginal slings over the Burch then, is that correct, yes or no?
MR. CARTMELL: You can answer it how you want to.
BY THE WITNESS:
A. It states, we recommend pubovaginal slings to maximize cure rate. And I recommend pubovaginal slings to maximize cure rate in patients that have recurrence of stress urinary incontinence. So I'm using the recommendations the way they are -- the recommendations -- you know, consistent with these recommendations.
BY MR. SNELL:
Q. Okay. So you think you are practicing within the standard of care then in the way you offer the pubovaginal sling to your patient cohorts?
A. Yes.
Q. And this systematic review and metaanalysis by Schimpf found for dyspareunia the retropubic sling had a lower rate than the pubovaginal

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sling, correct, yes or no?
A. According to this, yes.
Q. With regard to wound infections, this study -- strike that -- this systematic review and metaanalysis found the retropubic sling had a lower rate than both the pubovaginal sling and the Burch, correct?
A. That perioperative complication, yes.
Q. What types of wound infections are avoided with the use of the retropubic TVT device in the treatment of stress urinary incontinence?
A. A wound infection in the perioperative period.
Q. This systematic review also reported that the Burch had a higher rate of bowel injury than retropubic TVT sling, correct?
A. Yes, and they included a study on laparoscopic Burches which -- or actually three studies on laparoscopic Burches because the open Burch is not performed into the peritoneal cavity where a laparoscopic Burch is placing a trochar in through the peritoneal cavity. The three laparoscopic Burch papers would comprise the -- if not all, the majority of bowel injuries.

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Q. Remind me, do you do the -- you don't do the laparoscopic Burch?
A. No.
Q. Is it because you don't want to get into the bowel and have that perioperative morbidity from that significant type of potential complication?
A. That is one and also I don't find it as effective.
Q. What are the negative attributes of doing a laparoscopic Burch?
A. It is a longer operation, you have to insufflate the peritoneum, you have the risks associated with a laparoscopic procedure, such as putting a trochar in -- well, if you do it as an open procedure, you have a direct visualization of the trochar going in. Not everybody utilizes the open trochar insertion technique and, therefore, would be placing a trochar blindly, but the majority of surgeons are using the -- exclusively using the open technique for insufflating.
Q. This bowel injury, the one event out of the 32 patients, is it your testimony that you are certain that was a report of a series of patients who underwent laparoscopic Burch?

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A. It would be more likely than not that that was due to the laparoscopic procedure.
Q. As you sit here today, though, you don't know the exact study that they were referencing?
A. Not specifically, no.
Q. In this SUS systematic review and metaanalysis, there was a lower rate of ureteral injury with the retropubic sling as compared to the pubovaginal sling in the Burch, correct?
A. That's what they state, yes.
Q. How does one injure the ureter under direct visualization in the open Burch procedure?
A. Well, again, having done a significant number of Burch procedures and not having injured the ureter, one would probably be putting the stitches in the wrong place.
Q. Is it below the standard of care to have a ureteral injury in an open Burch procedure?
A. No, as long as it is recognized and timely repaired.
Q. Well, under direct visualization, shouldn't a surgeon not hit the ureter?
A. Well, you actually don't see the ureter during the Burch procedure, so that if there is

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scarring or some other anatomic variation, one could get the ureter by -- without knowing that they were putting the sutures through the ureter, which is why we do cystoscopies after the procedures.
Q. Well, one option, you could dissect down to the level of the ureters to make sure that you are not putting your sutures through them, right?
A. Right, but that would increase morbidity.
Q. How?
A. By dissecting down to the ureters, you can devitalize the ureter. You can disrupt its blood flow.
Q. I take it then in your Burch procedure -- strike that.
When you do the Burch, do you dissect down to the level of the ureters?
A. No, because I do a modification of the Burch where the stitches are placed far enough lateral where they would not be anywhere near the ureters.
Q. But it's not against the standard of care to place the stitches at some other location where the ureter could be sutured?
A. That is correct.
Q. In the systematic review and metaanalysis

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for retention lasting less than six weeks as well as retention lasting more than six weeks, the pubovaginal sling in the Burch had higher rates compared to the retropubic TVT, correct?
A. That is correct.
Q. And there is utility in the TVT having less retention postoperatively before six weeks and then after six weeks, correct?
A. Yes. However, the study also found that return to the operating room for urinary retention was much higher in the retropubic sling group so that this shows that the -- any retention from the Burch procedure resolved on its own and did not require return to the operating room, which would be a significant adverse event, which is summarized in the conclusions that the Burch procedure may result in lower rates of long-term adverse events such as return to the operating room for retention or erosion, return to the operating room for overactive bladders or return to the operating room for groin pain.
Q. They said may, correct?
A. That is correct.
Q. The pubovaginal sling had a higher rate of return to the operating room for urinary retention

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than the Burch, correct? Than the Burch, correct?
A. That is correct.
Q. And the retropubic TVT sling, correct?
A. That is correct.
Q. And that's the utility of the TVT as compared to the pubovaginal sling, correct?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. It is also a utility of the Burch.
MR. SNELL: Move to strike.
BY MR. SNELL:
Q. Can you answer my question yes or no?
A. Yes.
Q. And then if you have a caveat, you can add it now.
A. It is also a utility of the Burch.
Q. Fair enough. I want you to get your fair answer in. I would just like a responsive answer first, that's all.
For bladder perforation, the pubovaginal rate was 2.3 percent, the Burch was 2.8 percent, and the retropubic sling was 3.6 percent, correct?
A. That is correct.
Q. Now, the Burch looked at 10 studies and

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the retropubic sling had 41 studies, correct?
A. That is correct.
Q. So bladder perforation was actually for all of the different options one of the more commonly assessed complications, right?
A. That is correct.
Q. And the retropubic was about .8 percent higher than the Burch, right?
A. Yes.
Q. But the Burch is an open procedure, right?
A. Unless you are doing it laparoscopically.
Q. Fair enough.
And how many of those -- strike that.
Have you done an analysis to ascertain how many of those 19 bladder perforation events reported in the Burch arm were -- occurred in the open or the laparoscopic Burch series?
A. No, I have not.
Q. Even under direct visualization in an open Burch, you can still perforate the bladder, right?
A. That is correct.
Q. Have you done that?
A. No.
Q. Is it against the standard of care if a

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surgeon perforates the bladder during an open Burch?
A. As long as it is recognized and timely repaired.
Q. No, it's not?
A. It is not as long as it is recognized and timely repaired.
Q. And why is that?
A. Because any surgical procedure, an injury to a vital organ can happen. As long as it's repaired, it would not -- recognized and repaired, it would not fall below the standard of care.
Q. Well, if part of the justification for doing a Burch procedure to a patient is this is an open procedure and I can see down and see what I'm doing better than the blind steps that may be accommodated by doing a pubovaginal sling, like Dr. Blaivas does, or a midurethral TVT sling, but that surgeon hits one of those organs while doing this open procedure, that's not against the standard of care?
A. As long as it is recognized and repaired.
Q. Deep vein thrombosis was also lower with the retropubic TVT than the pubovaginal sling or the Burch, correct?
A. That is correct.

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Q. Have you ever had a DVT in your patient when you were doing a Burch?
A. No, I have not.
Q. When one does a longer open stress incontinence surgery, does that increase the risk of a DVT?
A. As I stated earlier, it depends on how much longer the procedure is.
Q. What if the patient has a coagulation disorder?
A. Then that patient would be anticoagulated.
Q. So it wouldn't matter?
A. It would matter, but that patient would be anticoagulated for either procedure.
Q. Vaginal perforation occurred in 2. -- .2 percent of the Burch group.
How did -- how do you perforate the vagina when you are doing the Burch?
A. When you are trying to elevate the bladder neck in order to place your stitches, you can put up your finger through the vagina or you can have your stitch create a defect in the vagina.
Q. When you were doing the TVT retropubic device, did you see any -- strike that.

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So if we go back in time when you were doing the TVT retropubic device, did you observe that you had less blood loss during the procedure as compared to your Burch colposuspension?
A. No.
Q. Have you seen it reported in the literature that there is less blood loss with the TVT retropubic compared to a Burch or a pubovaginal sling?
A. In the Schimpf paper, estimated blood loss of greater than 200 cc's, the highest was the retropubic. Transfusion was higher for retropubic and pubovaginal slings than the Burch. Hematomas were higher in retropubic than the Burch and pubovaginal slings.
Q. I think you misspoke.
So in the Schimpf, the estimated blood loss greater than 200 ml, they did not include data on Burch or pubovaginal sling, correct?
A. They -- there was no reports of a blood loss greater than 200 ml's.
Q. For transfusion, the Burch had a lower reported rate, 0 versus 0.4 percent for retropubic, but the pubovaginal had a higher rate than both at 1.9 percent, correct?

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A. That is correct.
Q. And then for a hematoma -- and what's a -- and a hematoma is a large collection of blood?
A. That is correct.
Q. Somewhere where you don't really want it to be?
A. That is correct.
Q. And for that hematomas, the retropubic actually had a lower rate than the Burch and the pubovaginal sling, correct?
A. I did misspeak.
Q. That's okay.
Doctor, the Demerci paper, have we studied -- have we covered this paper? I think we have.
A. Four times.
Q. Four times, yeah.
That's a study that's got dyspareunia and long-term follow-up with the Burch colposuspension, right?
A. According to what the title is, but we don't really -- there is no numbers that actually talk about long-term follow-up.
Q. I think you misspoke now.

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A. We've already talked about it.
Q. So whatever you testified before you'll stand by?
A. Yes.
Q. And if I attach the study and it reports the cohort assessed at 1.5 years and the cohort assessed at 4 years, you will maintain that they didn't report on longer term follow-up?
A. They report on longer term follow-up, but they don't talk about there is a difference between what was reported at one point versus what was reported at another point. That's what we talked about before.
Q. Right. They unfortunately or fortunately, they just say that there were a number of patients who had dyspareunia, and you and I don't know whether that occurred at 1.5 years or 4 years or somewhere in the middle, right?
A. Right. What we do know from the Schimpf paper is that the adverse event of returning to the operating room for groin pain was higher in the midurethral sling group compared to the Burch group.
Q. I'm not seeing, Doctor, where there was return to the operating room for groin pain?

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A. It's listing the long-term adverse events where they list returning to the operating room. So, Burch procedure may result in lower rates of return to the operating room for retention, erosion, overactive bladder symptoms and groin pain. That is Table 4.
Q. Right. But I'm looking at the actual data. And I didn't see where they reported return to the operating room for groin pain?
A. Well, that's what the Table 4 states.
Q. I know it states that and it says may, but I'm asking you then, where are the data in this report that shows what rate Burch had a return to the OR for groin pain, the percentages?
A. That I don't see.
Q. I didn't see that either.
(WHEREUPON, a certain document was marked Rosenzweig Deposition Exhibit No. 12, for identification, as of 09/22/2015.)
BY MR. SNELL:
Q. Have you reviewed these updated AUA stress incontinence guideline tables?
A. I have reviewed these, yes.
Q. Was the first time you reviewed these

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after Dr. Blaivas' recent deposition?
A. I can't recall when the first time I saw this was.
Q. You are aware that the AUA published their stress incontinence guidelines around 2009, 2010 and these are the updated tables that were revised as of 2012?
A. The copyright date is 2009 on this.
Q. If you look at page 4, you see that this was revised in 2012?
A. That is correct.
Q. And so if we look at Table A16 where we are now focusing on complication rates with prolapse -- let me just rephrase that. That was bad.
Table A16 reports complication rates of various stress urinary incontinence surgeries when those surgeries were done without concurrent prolapse, correct?
A. That is correct.
Q. Compared to the earlier tables where you have concurrent prolapse data referenced in it Appendix A11, correct?
A. That is correct.
Q. So if we're focusing on Appendix A16, the

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Burch colposuspension, you see it's dead center in the page that begins with, "The retropubic suspensions"?
A. Yes.
Q. And for the Burch there was -- it reports 6 percent of patients with pain, correct?
A. Yes.
Q. And that's -- that's not over in the laparoscopic suspension table, that's in the Burch suspension table, right?
A. Yes.
Q. And 3 percent of those patients had sexual dysfunction, correct?
A. Yes.
Q. And if you look over to the midurethral slings, the rate of pain for synthetic at the midurethra was 1 percent, correct?
A. Yes.
Q. So if you just flip back three pages.
So according to the AUA stress incontinence guidelines, the rate of pain and sexual dysfunction were lower with the synthetic sling at the midurethra compared to the Burch colposuspension, correct?
A. That's what they reported.

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Q. And data that reports the synthetic midurethral sling having a lower rate of pain and sexual dysfunction than the Burch would be a benefit for the midurethral sling, correct?
MR. CARTMELL: Object to form.
BY THE WITNESS:
A. Again, we don't have the references that are associated with it to go back and look at what these studies were, but the way this is reported, that would be a benefit.
BY MR. SNELL:
Q. Just like you were quick to point out that in the Schimpf paper there was 1 to 2 percent difference in the rate of return to the operating room from voiding dysfunction, right?
A. That is correct.
Q. And so you are certainly aware that there are data out there that are contrary to your opinion that the risks outweigh the benefits of the TVT, correct?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. I -- when you look at the studies on complications and the studies like the Petri study,

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the Abbott study, the Agnew study that look at the risks of sling procedures and the time where it takes the complications to show up, there may be data that is looking short term and does not track all of the complications.
BY MR. SNELL:
Q. However, I think you already told me, but papers like the Petri paper and the Abbott, those are case series of women who have complications who are referred to a tertiary care center, correct?
A. That is correct.
Q. And the own text of those studies, they say we don't know what the denominator is, therefore, we cannot draw any conclusions as to the incidence of these complications, correct?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. They do not have a denominator, that is correct.
BY MR. SNELL:
Q. And they acknowledge, that, therefore, they cannot state what the incidence of these complications are with the midurethral sling, correct?
MR. CARTMELL: What paper are you talking about?

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THE WITNESS: Petri.
MR. SNELL: Petri.
BY MR. SNELL:
Q. That's correct, right, Doctor?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. That is correct.
BY MR. SNELL:
Q. And, actually, Abbott, they also say that they cannot state what the incidence of those complications are because they do not have a denominator, correct?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. That is correct.
BY MR. SNELL:
Q. And they actually state that that is a "very important" limitation to the Abbott study, right?
MR. CARTMELL: Do you have the study?
BY THE WITNESS:
A. Do you have a copy of the Abbott to --
BY MR. SNELL:
Q. Yeah, let's get it out. I wouldn't

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misrepresent it to you.
(WHEREUPON, a certain document was marked Rosenzweig Deposition Exhibit No. 13, for identification, as of 09/22/2015.)
BY MR. SNELL:
Q. So, Doctor, we've pulled out the Abbott paper you were referring to, correct?
A. Yes.
Q. And if you'd turn back to page e7, they begin talking about all of the limitations on the study, right?
A. Yes.
Q. And they say, "Perhaps most importantly, there is no denominator," right, "for the total number of patients who underwent an SUI or POP procedure with synthetic mesh. Thus, we can make no comments about the rate at which such complications occur."
I read that correctly?
A. That is correct.
Q. And that's consistent with the disclaimer and the limitation referenced in the Petri study that you've already acknowledged, right?
A. That is correct.

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Q. And what this paper also states is that, "those women with complications after a sling-only procedure were treated more often with medical treatment first and rarely required surgical reintervention," correct?
A. What page are you on?
Q. The page just before that, e6. Do you need me to -- I can direct you there. I don't want you to think I'm making something up. It is on the right column.
A. Yes.
Q. So that's what the authors state, correct?
A. That's what they state, yes.
Q. And if we turn back to the AUA guidelines for the autologous slings, you don't use bone anchors, right?
A. That is correct.
Q. People don't really use bone anchors anymore anyways, right?
A. No.
Q. That's a rarity.
So autologous slings without bone anchors, that's the first column under Slings. Do you see that?

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MR. CARTMELL: What page?
BY THE WITNESS:
A. Without bone anchors?
BY MR. SNELL:
Q. Yeah.
A. Yes.
Q. So -- and just so we are all clear, we are looking at these tables of A16, first they address the retropubic suspensions, then the slings, particularly autologous and bone anchors, and then later they get to midurethral slings, right?
A. Yes.
Q. So the autologous fascial slings without bone anchors, the rate of pain was 10 percent, correct?
A. That is correct.
Q. And that was higher than both the Burch and the midurethral sling, correct?
A. Yes.
Q. And have you found a rate of pain higher with autologous slings compared to your Burches?
A. No.
Q. Okay. The autologous fascial sling without bone anchors had a rate of sexual dysfunction

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of 8 percent, correct?
A. That is correct.
Q. And that's a bit higher than the Burch suspension and the midurethral sling, correct?
A. What's quoted in this monograph, yes.
Q. And you're aware that Dr. Blaivas was one of the doctors involved in formulating and drafting this monograph, right?
A. His name is on the panel, yes.
Q. And so if one were to look at and rely upon these updated stress incontinence guidelines from the AUA, they would stand for the conclusion that with an evidence-based approach like the AUA took, the rate of pain and sexual dysfunction is lower with midurethral slings than the Burch and the pubovaginal sling --
MR. CARTMELL: Objection.
BY MR. SNELL:
Q. -- without bone anchors, correct?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. Again, on this monograph it doesn't describe the review that they did, the papers that they looked at, so without that it would be difficult

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to state with a reasonable degree of assuredness that there -- that that conclusion is valid.
BY MR. SNELL:
Q. And that's not an analysis that you've done yet, correct?
A. That -- an analysis of the studies that they've looked at?
Q. Yes. You have not done an analysis of the methodology of the AUA stress incontinence guidelines to say that their results that they've reported are incorrect?
MR. CARTMELL: I just want to make it clear. You are asking him if he did an analysis of what the AUA committee did?
MR. SNELL: Yes.
BY THE WITNESS:
A. It is not described in here, so it would be difficult to use a methodology such as reviewing the papers, looking at the quality of papers, seeing what papers that were looked at and were not looked to draw the same conclusions that they did.
BY MR. SNELL:
Q. I don't want you to get caught up in Exhibit 12 that I have a given you because this is an

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excerpt from a document that's about 500 plus pages.
MR. CARTMELL: Well, that may be part of the problem because you gave him one excerpt of a 500 page --
MR. SNELL: You are doing a speaking objection.
MR. CARTMELL: I want the record to be specifically clear that you have given him a 5-page document --
MR. SNELL: Yes, I did.
MR. CARTMELL: -- or whatever, six, seven page document from a 500-page document that he has not been entitled to review today.
MR. SNELL: Oh, wait. Let's just make the record clear. Stop giving speaking objections.
MR. CARTMELL: That's not an objection. It is a statement for the record.
MR. SNELL: That's a speaking objection.
BY MR. SNELL:
Q. Doctor, you told me that you had reviewed the updated AUA stress urinary incontinence guidelines, didn't you?
A. Yes.
Q. From 2012, right?
A. Yes.

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Q. You actually have read the 2009 guidelines, lead author Dmochowski, right?
A. Yes.
Q. And that was published in the AUA's journal, correct?
A. Yes.
Q. And did you assess their methodology in that paper?
MR. CARTMELL: Object to the form. It is vague and ambiguous. What do you mean assess their methodology? It makes no sense.
BY MR. SNELL:
Q. Did you assess their methodology in their systematic review?
A. To look at all of the individual papers to determine the quality of papers, which ones were included and which ones weren't, I probably did that at the time. I don't remember that specifically.
Q. And for complications, do you recall that they link to the AUA's website for the data tables that I have printed out here?
A. Yes.
Q. And you've been on the AUA's website and you've looked at that 500-plus page document that

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updates the 2009 report, correct?
A. Yes.
Q. Have you actually printed out the 500-page tables?
A. No.
Q. But you've at least looked at them, right?
A. Yes.
Q. You certainly haven't brought them here today, have you?
A. No, I have not.
MR. CARTMELL: And that's was my point for the record is what you gave him is not the entire thing. That's the only point I'm making is he doesn't have it here today to look at.
MR. SNELL: That's not my fault. I asked you to bring your file and everything and you didn't bring it. So that's my fault, Tom. I'm not printing out 1500 pages of documents.
MR. CARTMELL: I wasn't attributing fault to anybody. I was just making the point that it is not here. You are asking very specific questions about a document that is not here.
BY MR. SNELL:
Q. When you went back and you read the

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update, the 2012 update to the AUA guidelines, that 500-plus page document, did you look at the AUA panel's description of their methodology for how they came to calculate these complication rates?
A. I don't recall specifically what they stated. If we have that, it would be important to look at so I can answer the question.
Q. My question was:
When you read the updated AUA guidelines from 2012, did you read the panel members' description of how they calculated and assessed these complication rates?
A. I looked at that. I don't recall specifically what they described.
Q. Fair enough. Okay.
But you do recall it being described in the body of that very large document?
A. More likely than not, yes, it was there.
Q. And as you sit here, you do not recall any problems with their methodology as they described it?
A. Not that I recall.
Q. Fair enough.
MR. SNELL: All right. Let's go off the record.
(WHEREUPON, a recess was had

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from 5:00 to 5:03 p.m.)
MR. SNELL: Let's go on the record.
BY MR. SNELL:
Q. Those studies in the AUA's stress incontinence guidelines updated in 2012 do report benefits with the midurethral sling over pubovaginal and Burch for some complications, agreed?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. Perioperative complications for the Burch, yes.
BY MR. SNELL:
Q. And actually, dyspareunia and pain and sexual dysfunction were all higher with the pubovaginal sling and the Burch compared to the midurethral sling, correct?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. Only in the AUA 2012 update.
BY MR. SNELL:
Q. I believe you are wrong. If you want to look at Schimpf, you'll see that the rate of dyspareunia was higher with the Burch and the pubovaginal sling than the TVT midurethral retropubic

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sling.
MR. CARTMELL: Object and move to strike the statement of counsel. If you want to ask him questions, then do that.
BY THE WITNESS:
A. In the Schimpf paper there was no reports of dyspareunia in the Burch and no reports of dyspareunia in the retropubic.
BY MR. SNELL:
Q. There was a higher rate of dyspareunia with the pubovaginal sling, correct?
A. That is correct.
Q. And those are benefits in light of the TVT's design and in particular how the design is carried out and placed in a woman, correct?
MR. CARTMELL: Wait, wait. Object to the form, misstates the evidence, misstates his prior testimony misstates the article.
BY THE WITNESS:
A. This study showed 0 dyspareunia for the retropubic slings, which I think is -- from what other studies have shown, such as the highest -- one of the highest rates of complications from slings, such as the Abbott paper, the Petri paper is pain and

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dyspareunia, it is very unlikely to see 0 percent dyspareunia for the retropubic sling.
MR. SNELL: Object and move to strike.
BY MR. SNELL:
Q. In the Schimpf paper they are reporting on incidence, right?
A. That is correct.
Q. They have an enumerator and a denominator, right?
A. That is correct.
Q. Not to beat a dead horse, but we've already agreed, I thought, that Abbott and the Petri papers don't have denominators and don't talk about incidence, right?
MR. CARTMELL: Object; asked and answered.
BY THE WITNESS:
A. They talk about the number of patients that have a complication, that is correct.
BY MR. SNELL:
Q. But they don't talk about the incidence, right?
A. That is correct.
Q. So in these papers, the retropubic DVT midurethral sling had a lower rate of dyspareunia than

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the pubovaginal, and that would be attributable to its design, correct?
A. But it was --
Q. Can you answer yes or no and then give me --
MR. CARTMELL: No, no. We are going to walk out of here.
MR. SNELL: That's fine. I'll go right to the judge.
MR. CARTMELL: Stop interrupting him.
MR. SNELL: I'll go right to the judge.
MR. CARTMELL: I'm so fine with you going to the judge. Call him right now, all right. You are going to stop interrupting him. You do it again, we're done. Let him answer the question. Then if you want to move to strike, then I'm going to let you do that or you can ask it again. I'm tired of you interrupting him, all right.
MR. SNELL: Did you not -- let me ask you this:
Did you not tell him Judge Eifert's orders and instructions about being responsive, answering yes or no and then you can give caveats until the cows come home? Does he know that or not?
MR. CARTMELL: No, you --

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MR. SNELL: If he doesn't know that, I'm not going to take it out on him. I'm going to let him answer however he wants to answer.
MR. CARTMELL: You weren't there for Judge Eifert's instruction. I was on the phone with Judge Eifert. Your side has misstated what Judge Eifert has said for months, if not years, okay. So don't tell me what she said.
The rule is this. You ask him a question, he answers it. Just because you don't like his answer doesn't mean you get to interrupt him in the middle of it, which you've done multiple times today. So let him --
MR. SNELL: I want to hear my question.
MR. CARTMELL: -- give a response and then if you don't like it, you can strike it, and I've given you leeway all day to ask it again.
MR. SNELL: Can you, Madam Court Reporter, can you read back my question.
(WHEREUPON, the record was read by the reporter as requested.)
BY MR. SNELL:
Q. Okay. Now answer, please, however you want to answer.

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A. No.
Q. And why do you say no?
A. It's attributable to studies not reporting dyspareunia, studies not having a long-term follow-up to show dyspareunia, and we know that patients complained of dyspareunia after retropubic slings, and to say that there are -- there is no dyspareunia after retropubic sling is not realistic. And they only cite two studies out of all of the studies on retropubic slings to quote the rate of dyspareunia.
Q. So if I understand you correctly, you don't disagree that the retropubic sling in this analysis had a lower rate of dyspareunia than the pubovaginal sling?
A. The two studies that they looked at that showed -- that reported on dyspareunia compared to the five papers on pubovaginal slings is not representative from what we've described before as the body of literature on retropubic slings. I'm not disputing what the table shows. I'm just disputing that that is representative of the data.
MR. SNELL: Move to strike as non-responsive.
BY MR. SNELL:
Q. In the AUA guidelines, in the updated

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table in particular that we were looking at, A16, there is a 16 -- strike that -- there is a 6 percent rate of bladder injury with the Burch suspension, correct?
A. That's what the table states.
Q. And the laparoscopic Burch had a 5 percent rate of bladder injury, correct?
A. That's what this table states.
Q. And so according to the AUA's analysis, the rate of bladder injury with the Burch is roughly the same, 5, 6 percent, whether you do it open or laparoscopically?
A. That is correct.
Q. And is that a finding that you disagree with?
A. I would say that from my -- I would say that it would be higher for the laparoscopic Burch but probably not significantly higher.
Q. If there is a bladder injury during the laparoscopic Burch, can that be serious?
A. If it's not recognized and timely repaired.
Q. If there is retention after a Burch colposuspension, an open Burch colposuspension or a

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laparoscopic Burch that requires the surgeon to make a modification to the Burch, does the surgeon need to do that by opening the retropubic space or can that be done transvaginally?
A. If --
Q. So if there is a problem with retention postoperatively following either type of Burch colposuspension and you have to take down the Burch -- is that something that you've ever had to do?
A. Yes.
Q. Okay. Is that accomplished transvaginally or do you have to reopen up the retropubic area?
A. You can do it either way.
Q. How do you do it?
A. I've done it vaginally and I've done it open before.
Q. Do both ways work the same?
A. If you are trying to do a urethrolysis, a urethrolysis probably would be better done open.
Q. And why would that be?
A. You can get better exposure and a better dissection.
Q. I know you've told me in the past complications that you believe can flow from

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degradation of the mesh.
My question to you is:
Have any of those complications been reported to be due to degradation in any prospective study in women undergoing treatment for stress urinary incontinence?
A. Have the studies on treatment for complications of stress urinary incontinence stated that there is degradation of the -- of the mesh?
Q. I think you are changing my question around.
A. Well, I was asking for clarification --
Q. Okay. Fair enough.
A. -- because I didn't understand it.
Q. That's fair.
A. Which is why when I repeated it back it became even more convoluted, so.
Q. You threw me off there. Let me see if I can rephrase it. Thank you for that.
So you've testified, and I'm not going to rehash it, that you believe that degradation can lead to certain complications. I think one of them is erosion or exposure.
My question is this:

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Are you relying on any prospective studies in women undergoing TVT implantation for stress incontinence that report that the complication was due to degradation of the mesh?
A. Wang 2004.
Q. Say it again?
A. Wang 2004, American Journal of Obstetrics and Gynecology. Recurrent erosions were associated with mesh degradation, fragmentation of the mesh, and Dr. Wang concluded that this needed to be looked at on a prospective basis.
Q. And was Wang 2004 reported or cited in your --
MR. CARTMELL: Yes, and you've gone through it with him before in prior depositions.
BY THE WITNESS:
A. Yes, we have gone through this before in prior depositions.
BY MR. SNELL:
Q. So this is the only study you can cite to for the proposition that in women with clinical follow-up with TVT used for the application of stress incontinence that degradation leads to complications?
A. You said prospectively. This was a

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prospective study, yes.
Q. Okay. Correct me if I'm wrong, but in that study they did not do a multivariate analysis of patient factors and surgeon factors in the assessment of which factors after assessment were statistically significantly associated with the 2.4 percent rate of defective vaginal healing?
MR. CARTMELL: I'm going to give you a little bit of leeway here, that question, but you have gone through this study more than once with this doctor. Judge Eifert has been very clear that you are not supposed to be duplicative in your questioning of these experts. You've done it a bunch already today, so I'm shutting it down after that question.
BY THE WITNESS:
A. May I see the study to see if that is specifically described?
BY MR. SNELL:
Q. Sure.
(WHEREUPON, a certain document was marked Rosenzweig Deposition Exhibit No. 14, for identification, as of 09/22/2015.)
BY THE WITNESS:

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A. The answer to that question is no.
BY MR. SNELL:
Q. There was no --
A. But if I can explain, Dr. Wang, as we have talked about before, was part of the initial 510(k) submission, his data. He is one of the largest users of slings. So I would doubt that surgeon factor would be a significant cause of the erosions in this case.
Q. Well, mesh erosions can happen to experienced skilled surgeons, certainly, right?
A. That is correct because of the characteristics of the mesh.
Q. And his 2.4 percent rate is not outside of the overall body of literature, correct?
A. This is the recurrent erosions, not the simple-to-treat erosions.
MR. SNELL: Move to strike.
BY MR. SNELL:
Q. This 2.4 percent is not outside the overall medical literature reporting on mesh exposures, correct?
MR. CARTMELL: Objection; asked and answered.
BY THE WITNESS:
A. For recurrent erosions, no.

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BY MR. SNELL:
Q. And this study does not tell us what was the percentage of degradation, if any, that occurred?
A. In the patients with defective healing, the inflammatory process was accompanied by pronounced peri-filamentous fibrosis and foreign body reaction. The histology showed mesh filaments were fragmented and surrounded by palisading histiocytes.
MR. SNELL: Objection; move to strike.
BY MR. SNELL:
Q. So this study does not tell us the percentage of mesh degradation, correct?
A. It does not give a specific number, no.
Q. It does not tell us the total volume of mesh degradation in this 2.4 percent of women, correct?
A. Correct.
Q. It does not compare and tell us what the histologic findings were in the 700-plus women who did not a mesh exposure, did it?
A. The histologic findings?
Q. Yes.
A. No.
Q. Because you don't do histologic findings

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in women who don't have exposure and don't have complications, do you?
A. We reviewed a paper earlier that did, but in the majority of cases, no.
Q. Are there any clinical studies assessing TVT in women with stress urinary incontinence that reports that cytotoxicity of the mesh is a cause of their -- any reported complications?
A. Erosion is a sign of cytotoxicity.
MR. SNELL: Move to strike.
BY MR. SNELL:
Q. You are telling me stuff I already know you've told me before. I'm trying to be respectful with Tom over hear screaming at me.
MR. CARTMELL: You've asked that question you just asked too.
MR. SNELL: I haven't asked that question.
MR. CARTMELL: Yes, you have.
MR. SNELL: Read back my question, please.
(WHEREUPON, the record was read by the reporter as requested.)
MR. CARTMELL: Objection; asked and answered. If you need to tell him again, tell him again.
BY THE WITNESS:

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A. Erosion is a sign of cytotoxicity.
MR. SNELL: I'll move to strike again.
BY MR. SNELL:
Q. I'm asking you for clinical studies, all right. Are there clinical studies -- I'm not asking you what your opinion is about whether erosion is a sign of cytotoxicity or not.
So can you not --
MR. SNELL: Can you reread my question one more time.
(WHEREUPON, the record was read by the reporter as requested.)
BY THE WITNESS:
A. No.
BY MR. SNELL:
Q. You earlier stated that erosion is a sign of cytotoxicity in your opinion. Just so I'm clear, were you referring to mesh exposure or the erosion of the mesh into the bladder or urethra?
A. Either one. And the scientific studies that show that are the Moalli papers on apoptosis and cell death associated with heavyweight mesh.
Q. Those are not papers in women though, right?

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A. That is correct.
Q. I'm trying to think of a way to ask this question.
If a woman -- if a woman has a mesh erosion or mesh exposure -- strike that.
Let's say there was a study and an analysis done and it reported a 2.2 percent rate of vaginal mesh exposure, okay.
You are with me so far?
A. Yes, sir.
Q. And numbers similar to that that Dr. Blaivas reported in Table 3 of his 2015 review article for retropubic slings, okay?
A. Which is probably an underestimate of the total number of erosions, but go ahead.
Q. So if we extrapolate that out, let's say that will be 22 women out of 1,000 women, correct?
A. That have been followed up to find their erosion, yes.
Q. So here is my question. So if we take those 22 women, is there a scientifically reliable study or studies in women who have received the mesh that would allow one to say which of those 22 women had the erosion or exposure because of cytotoxicity or

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was it due to some other reason?
Do you understand my question?
A. Yes. It could be due to degradation, it could be due to mesh contraction, chronic foreign body reaction, chronic inflammation or cytotoxicity. For me to sit around and say what percentage would be cytotoxicity, what percentage would be degradation, that is impossible to do. We know all of those mechanisms can lead to mesh erosion or mesh exposure, however we want to describe that.
Q. But as you sit here, you can't say which of those particular mechanisms, you call it degradation, contraction, inflammation, cytotoxicity, produce an exposure in a particular woman?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. Also I would add roping and fraying along with that.
BY MR. SNELL:
Q. So roping and fraying. You can't say for all of those mechanisms which one leads to a mesh exposure in a particular woman, correct?
MR. CARTMELL: Object. Are you asking -- for clarification, are you asking about in a study or are

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you asking about --
MR. SNELL: You are giving a speaking objection, Tom. Knock it off.
MR. CARTMELL: No. I need to know what you are talking about.
MR. SNELL: Knock it off.
MR. CARTMELL: It makes no sense. You were talking about a study, you were saying hypothetically there is 2.2 percent rate. If you are asking him in a particular patient that's in front of him or he's treating, can he figure that out, or are you asking him in a study by looking at a paper? That's what -- it's vague and ambiguous, it lacks foundation, it calls for speculation until you tell him that.
BY MR. SNELL:
Q. You have identified different potential mechanisms by which you believe exposures can occur, namely, degradation, contraction, chronic inflammation, cytotoxicity, roping and curling?
A. And fraying.
Q. And fraying. So we've got seven, right?
A. Yes.
Q. Can you say which of those mechanisms caused an exposure in a particular woman?

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A. In a particular woman, no.
Q. Can you say which of those mechanisms caused an exposure in a group of 20 women who had exposures?
A. If I had the mesh under a microscope where we could see that there was roping, fraying, curling, particle loss, degradation, contraction and deformation, then any one of those would have caused that.
Q. So you would need the mesh to be assessed under a microscope?
A. To know the exact mechanism, it would be very helpful to see what the microscopic findings were.
Q. Because -- and are you saying a scanning electron microscope or just the regular pathology microscope?
A. The SEM would be able to tell you if there is degradation. The lower power microscope can show you if there is roping, fraying, curling and contraction of the mesh.
Q. Well, the SEM shows the surface irregularities on the mesh, correct?
A. No. It shows breaking of the mesh,

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flaking of the -- or fragmentation of the mesh. We've had this discussion before about surface irregularities, Burt. Oh, excuse me. Sir.

Q. That's okay. Oh, I think you're -- with all respect, I think you are actually changing what you had told me before.

A. No, not at all.

Q. You have not mentioned breaking of the mesh. So let me back up.

When you and I have discussed degradation -- and we've discussed degradation and your support for it that you believe comes out of the human data from Clave, right?

A. And all of the other references that are in my report, yes.

Q. But I'm not worried about dogs and all of that stuff, all right. I'm talking about in humans for a pelvic application, particularly stress incontinence, and you've told me --

A. There are more than just the Clave study on my reliance list of meshes. There is the Zimmer paper, there is a variety of other pathologic papers that look at the -- the cracking, fragmentation of the mesh looked at under an SEM.

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MR. CARTMELL: And you have talked about all of that in prior depositions.

BY MR. SNELL:

Q. I have talked to you, but there was no discussion about breaking of the mesh.

MR. CARTMELL: That's a misstatement of his prior testimony.

BY THE WITNESS:

A. Completely in half?

BY MR. SNELL:

Q. Yes, the breaking of the mesh, unless I'm -- unless -- and I'm not trying to mess with you. I'm serious.

A. Breaking as I described it before?

Q. Yeah. So in the Clave paper and Philippe Zimmer's paper that didn't find oxidation, in none of the human papers data assessing stress incontinence meshes did they show the mesh breaking?

A. And what your --

Q. Is that correct or not?

MR. CARTMELL: Let him answer the question.

BY THE WITNESS:

A. What you are saying is broken in half or that it's broken on the surface? That's what I'm

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saying.

BY MR. SNELL:

Q. Okay. So, yeah, broken in half, broken such that it would impair its functionality?

A. Well, I've seen that clinically where the mesh has come out broken, yes.

MR. SNELL: Move to strike.

MR. CARTMELL: And he has testified to that multiple times.

MR. SNELL: Move to strike.

BY MR. SNELL:

Q. I know. I'm not asking about what you did clinically. I know what you did. I'm talking -- I'm trying to get clarification on the clinical literature.

A. This is the same --

Q. On the clinical literature.

A. This is the same testimony I have a given before.

Q. Well, I need to be clear before I leave here.

MR. CARTMELL: This is just an attempt to rehash old material you've gone through with him.

MR. SNELL: No.

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MR. CARTMELL: You are more than six hours into this and about four of it is stuff you've covered in the past.

MR. SNELL: No. This -- Tom, this needs to be -- I just want to be clear.

BY MR. SNELL:

Q. Because I know what you've said, you've seen it break when you went back on your patients and stuff. I'm not fussing with you on that.

MR. CARTMELL: And he has testified that Iakovlev's papers have shown breakage --

MR. SNELL: Are you testifying now? I think you are.

MR. CARTMELL: I am telling you what his testimony has been in the past because you are not supposed to keep covering that.

MR. SNELL: I think you are. You are speaking and you are literally testifying for him.

MR. CARTMELL: I am telling you --

MR. SNELL: You are augmenting the record for him. Why don't you go ahead and supplement some more.

MR. CARTMELL: I am telling you because you are not supposed to be going over what you have gone through in the past. Do you want me to get his

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deposition out and show you where it is?
MR. SNELL: Show me where he says that it broke such that it impaired its utility. That's a specific question on design, right?
MR. CARTMELL: Do you want me to find it?
MR. SNELL: I don't care. You can look for all you want to. This is my question so I know this before I leave here on degradation.
BY MR. SNELL:
Q. In the clinical studies in the literature involving women with a stress incontinence sling, are you saying that those data report breakage of the mesh such that it would impair the utility of the device?
A. Well, the patient ended up with a complication, so that impaired the utility of the device.
Q. I feel like we are going around here. I don't want to go around.
All of the patients in Clave had complications, yet only a third or half had supposed cracking, right?
A. Well, the ones that had their mesh removed less than three months did not have cracking, fragmentation. The ones after had a significantly

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higher rate.
Q. But you can't point to the fact that the patient had a complication and say it must have been degradation because she had a complication when half of the cohort didn't even have degradation as assessed by Clave.
Do you understand me?
MR. CARTMELL: Object. Asked and answered. You've gone over Clave for hours at trial and multiple times in depositions.
BY THE WITNESS:
A. And we discussed before that the patients that had their mesh removed in less than three months did not show degradation.
MR. SNELL: Move to strike as non-responsive. I don't know what to do with that. We'll just move on.
MR. CARTMELL: I'm not going to let him answer any more questions about Clave.
MR. SNELL: I'm just going to move on because I think it's not responsive at all.
BY MR. SNELL:
Q. Do you know what volume of the TVT mesh must degrade before it can produce an exposure?
A. Mesh filaments fragmented and surrounded

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by palisading histiocytes and multinucleated giant cells is enough to cause mesh exposure.
MR. SNELL: Move to strike.
BY MR. SNELL:
Q. Do you know what volume of the TVT mesh degrading is enough to produce a mesh exposure?
MR. CARTMELL: Objection; asked and answered.
If you need to tell him again, then go right ahead.
BY MR. SNELL:
Q. Do you know what volume I mean? When I say "volume", you're a scientist, a doctor, you know what volume is. I'm not talking about histologic slides. I'm talking about volume.
A. Are you talking about the percent fragmentation?
Q. Yes, volume, what volume of TVT mesh degrades -- must degrade in order to produce an exposure from that degradation?
A. According to Pariente, there is an 8.5 percent of particle loss from mesh. I would say that that is probably a good percentage.
Q. Okay. Pariente is not even a study that looked at meshes that had been in women, correct?

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A. That is correct.
Q. Fair enough.
MR. SNELL: Let's go off the record.
(WHEREUPON, a recess was had from 5:39 to 5:47 p.m.)
BY MR. SNELL:
Q. I'm trying to make this short so we can short-circuit a lot of stuff.
So you know how we've looked at metaanalyses and the clinical literature by Cochrane review and others, Novara, I know you know all of those papers, and in some of those papers they do assess, and so we've discussed some of them today where they've found that the multifilament mesh had a higher rate of erosions or the bottom-to-top had a higher rate, correct?
MR. CARTMELL: Objection; asked and answered. We are not going to rehash Cochrane. You went over it for an hour.
BY MR. SNELL:
Q. I'm not going to rehash, but you've seen that, correct?
A. I've seen that.
Q. So for all of these mechanisms that you've

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identified, degradation, contraction, chronic inflammation, cytotoxicity, roping, curling, fraying, okay, have you seen each of those mechanisms assessed in a reliable multivariate model that determines with the TVT and stress incontinence treatment that one or more of those variables plays a role in causing a complication?

A. Using a multivariate analysis?

Q. Yes.

A. To say in the Cochrane analysis or the Novara analysis?

Q. Or in the clinical literature overall that you've reviewed.

A. They haven't done multivariate analysis.

Q. Have they done univariate analyses in the clinical literature that you've reviewed that have reported that one of those seven mechanisms was a statistically significant cause of a complication?

A. In a prospective fashion?

Q. Let's take prospective first, yes.

A. Because there are retrospective studies that have shown that, you know, that we've talked about the Clave study, the Zimmer study that looked at degradation. We know that cytotoxicity, meaning cell

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death, when you see an erosion, there are plenty of studies that report erosions, that you see erosions, that is evidence of cytotoxicity.

MR. SNELL: I'm going to respectfully move to strike.

Can you reread the question?

(WHEREUPON, the record was read by the reporter as requested.)

MR. SNELL: And he said, In a prospective way? And my answer was, Yes, let's talk about prospective first.

BY THE WITNESS:

A. Not that I've seen in the literature.

BY MR. SNELL:

Q. You have seen studies in the clinical literature for TVT that assess factors like type 2 diabetes and whether after statistical analysis type 2 diabetes was a statistically significant factor in causing exposures, correct?

A. If you have a paper that you'd like to talk about, I'd like to see that.

Q. I don't have a particular one.

Have you seen that, though?

A. If you have a specific paper that talks

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about that there is a -- that diabetes was statistically significant in an individual patient or there are studies that talk about patient factors.

Q. Right.

A. Okay. And they opine about patient factors.

Q. And they assess patient factors with univariate and multivariate models to determine whether there is a statistically significant increased rate of a complication based on those factors, correct?

A. There are studies like that for POP mesh.

Q. You are not aware of any studies like that for stress incontinence mesh, particularly the TVT retropubic device?

A. If you have a particular study that you want to talk about?

Q. I don't. I'm just asking your knowledge.

A. There -- again, there are POP mesh studies that look at that, there are other papers that talk about patient factors as being -- and their association with complications.

MR. SNELL: Move to strike.

BY MR. SNELL:

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Q. Straight forward question.

Have patient factors been assessed in studies assessing exposure and other complications with the TVT retropubic device?

A. Patient factors have been assessed.

Q. Okay. And what patient factors are significant in increasing the rate of mesh exposure with the TVT retropubic design for treating stress incontinence?

A. Specifically in the retropubic design?

Q. Yes.

A. From what I recall is that studies that have looked at patient factors have looked at midurethral slings in general.

Q. So you are unable to point to any particular patient factors that increase the rate of mesh exposure with the TVT retropubic design?

A. Specifically?

Q. Yes, sir.

A. There are patient factors that have been associated with complications from midurethral slings in general.

Q. But is there an answer to my question?

A. Again, individual factors have been

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associated with complications, patient factors.
Q. But my question is very -- is focused on the TVT retropubic design. Can you point to any that are specific to that design?
A. To the design itself?
Q. Yes.
A. Are you talking about the heavyweight small pore?
Q. No, no, I don't want to hear the same litany of things.
What I'm asking for is what are the patient factors that statistically significantly lead to an increase rate of exposure with the TVT retropubic design?
A. Statistically significant increase in exposure?
Q. Yes, the patient factors.
A. Those factors haven't been elucidated statistically significant.
Q. So when you say there are patient factors that have been examined for midurethral slings in general, are there particular patient factors that have been found to statistically significantly increase the risk of exposure? And, if so, which ones

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are they in your opinion? And if you don't have an opinion, just tell me and I'll move on.
A. Statistically significant, I don't have an opinion about that.
Q. Fair enough.
If a larger weight, larger pore mesh were used as an alternative design for TVT such as you earlier stated, like Ultrapro, you will acknowledge that there is a risk that with five or ten years of duration or more, that product could have lower efficacy rates than had been demonstrated in trials with the TVT retropubic design, correct?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. More likely than not, no.
BY MR. SNELL:
Q. What's the basis of that statement?
A. That there was -- when you look at it for POP mesh, there is no difference in efficacy in the short term it's been studied.
MR. SNELL: Move to strike as non-responsive.
BY MR. SNELL:
Q. My question was focused on the longer term, not short term.

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You will acknowledge that there is a risk that if Ultrapro were used in the TVT configuration and it were studied out to five and ten or more years, that there is a risk that it may not work as well as TVT, yes or no?
A. No.
Q. And what is the basis for that statement, considering you've already told me there is no five-plus year data with Ultrapro in the application of stress incontinence?
A. Well, the three-year data --
MR. CARTMELL: Object to the form of the question. It is a statement by counsel. I move to strike it. You can ask him questions.
BY THE WITNESS:
A. The three-year data showed excellent efficacy. I can't see that degrading in two years after that.
BY MR. SNELL:
Q. The three-year data in Ultrapro versus prolene?
A. Yes.
Q. Not DVT as we've discussed?
A. That is correct.

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Q. What would be your methodology -- do you believe that the ten-year data on Ultrapro as a sling, would that be comparable to TVT?
A. Yes.
Q. What's your methodology for that statement?
A. To see the degradation curve with over three years, it does not look like it's any different from the TVT data, so my methodology is looking at the information that we have and assessing if there was a change in the degradation curve from TVT. And, therefore, since there is none that it would be a similar degradation curve longer.
Q. You're basing this on the single Okulu study?
A. Well, the part that degrades in Ultrapro is degraded long before we got to the three-year data. So if the efficacy is still there three years, it should follow the same curve as the TVT data.
Q. Why would you study a product beyond three years then?
A. Why --
Q. Why study a product beyond three years?
A. Well, when it is studied after three

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years, you will see that the efficacy will hold up.
Q. But that hasn't been demonstrated in the reliable scientific studies?
A. The Okulu study has not been carried out past three years.
Q. And that has not been demonstrated in any reliable scientific study that you are aware of in the entire world, correct?
A. The Okulu study has not been carried out past three years.
MR. SNELL: Move to strike.
BY MR. SNELL:
Q. Can you answer my question yes or no?
A. The Okulu study has not been carried out past three years.
MR. CARTMELL: That answers your question. Move on.
MR. SNELL: So you can't say yes or no, okay. Mark the record on this question.
MR. CARTMELL: Can you tell us how long we've been going, please?
THE COURT REPORTER: Six hours and 10 minutes.
BY MR. SNELL:
Q. In your opinion are there situations in

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which the TVT device should not be used which are not identified in the contraindications in the IFU?
A. What was known back in 1999 that it should be used with caution in patients that have had prior vaginal surgery, prior vaginal infections and vaginal scarring.
Q. You earlier mentioned Dr. Iakovlev, or I think counsel did, in supplementing your answer.
Do you rely on Dr. Iakovlev, his expertise in the review of pathology?
A. Do I rely on his expertise?
Q. Yes.
A. In what respect?
Q. For any opinions he has stated with regard to pathology.
A. Yes.
Q. For example, let's go ahead and mark it so we have a clear record then.
MR. CARTMELL: You are going to mark his paper, Iakovlev's paper that you have gone over with him before?
MR. SNELL: No, no, no. I'm going to mark Blaivas, Blaivas and Iakovlev.
MR. CARTMELL: You've gone over that with him.

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MR. SNELL: I haven't gone over that with him. It was just published like a couple of weeks ago.
BY THE WITNESS:
A. We already talked about that earlier today.
MR. SNELL: I didn't mark it.
MR. CARTMELL: But you've talked about it.
(WHEREUPON, a certain document was marked Rosenzweig Deposition Exhibit No. 15, for identification, as of 09/22/2015.)
BY MR. SNELL:
Q. That's been marked as what, Doctor?
A. 15.
Q. I just want to do something real quick for the record. This is the paper that you and I earlier discussed by Dr. Blaivas, Dr. Iakovlev and some others, correct?
A. Yes.
Q. And this is something you've reviewed, right?
A. Yes.
Q. Is this a paper that you are relying on for your opinions?

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A. It is a paper I've reviewed.
Q. Okay. So you are not relying on this paper by Dr. Iakovlev and Blaivas and others for your opinions?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. For my opinions in my report?
BY MR. SNELL:
Q. For your opinions, yes, in your report.
A. I don't reference this in my report.
Q. Okay. Is there anything unreasonable that I found in Dr. Blaivas and Iakovlev's report?
A. No.
Q. All right. And part of that report goes through histologic pictures and findings.
I guess my question for you is:
Would you rely on Dr. Iakovlev's analysis of those histology and pathology findings?
A. To describe what he found during those histological?
Q. Exactly.
A. Yes.
Q. Do you know why you weren't allowed to be -- or asked to be on this paper?

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A. Why I --
Q. Strike that. I've lost something there actually.
Were you asked to be an author to this paper that we've marked as Exhibit 15?
A. No.
Q. Why not, do you know?
A. I have no idea.
Q. You've met Dr. Iakovlev, right?
A. No, I have not.
Q. Never?
A. No.
Q. Okay. Fair enough. I'm not going to ask you any more about that one.
MR. CARTMELL: Would you give me one of those?
MR. SNELL: Did I give you one, yeah. I should have. If not, there it is. Let me just make sure it doesn't have a bunch of highlights and notes on it. 15.
Let me take a break.
(WHEREUPON, a recess was had from 6:05 to 6:11 p.m.)
BY MR. SNELL:
Q. Just a couple of quick questions and then

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I'll let you go.
So I noticed one of your opinions was that you were critical of the way that the TVT would be tensioned?
A. Yes.
Q. And you've described that, so I don't want to rehash it.
How would you recommend that the TVT would be tensioned, or do you have an opinion on that?
A. I think as I've stated in my report that it is impossible to describe tensioning. There have been several different descriptions on how to tension a device, such as putting an instrument between the sling and the urethra using was the DeLevao method of using a Babcock. However, there -- there is always going to be some element of tension on the sling once you're done placing it inside the female vagina.
Q. So if you are writing the IFU for TVT, you wouldn't have any special language on tensioning of the device?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. Well, I would not be putting in that it is tension-free.

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(WHEREUPON, Mr. Paul S. Rosenblatt exited the deposition proceedings.)
BY MR. SNELL:
Q. Describing how to carrying out the tensioning or de-tensioning, what words would you use?
A. No. 1, I would acknowledge that getting a tension or putting it in would be impossible to tension, to let the patient know that it is impossible to tension the device, that if there is a -- a problem with over tensioning, that the device might need to be incised or excised completely to treat their urinary symptoms. Even after removing the device or a piece of the device, it might not treat their symptoms.
MR. SNELL: I respectfully move to strike.
BY MR. SNELL:
Q. Would you describe -- what words would you use to tell the surgeon how to tension or de-tension the device?
A. Again, I would describe that it is impossible to know exactly how much tension or lack of tension there is on the device. And to explain to the doctor what the consequences are of not enough tension or too much tension so that they can give that information to the patient. As I've described the way

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I do my pubovaginal slings, I tell my patients I am putting this to give a degree of obstruction of their urethra and that they run the risk of needing a future operation to treat that so that the -- the patient has information that it might be impossible to exactly know the right place under the urethra in the midurethra to place the sling and, therefore, these are the risks that are associated with that part of the procedure.
Q. So you wouldn't attempt in the IFU to say, place the sling loosely at the midurethra, use some type of blunt surgical instrument to make sure the mesh is placed loosely?
A. All of those -- you know, whether you use a Babcock, whether you use a device, all of those have to be acknowledged as giving a best estimate that they are -- that it cannot be tensioned reliably, it CANNOT be -- it is not going in tension-free, that it is not tensioned when you need it, that this is a defect of the device that you cannot appropriately tension the device reliably, reproducibly, and that these are the consequences of that, as I've stated in my report.
MR. SNELL: I'm going to object. I think that was non-responsive again. I'm just going to move on.

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BY MR. SNELL:
Q. Have you analyzed the literature and seen any studies or do you know of data that reports on the percentage of surgeons in the urogynecology or gynecology field who rely upon an Instructions for Use?
A. Have I seen it published in a -- in an article about the number of doctors that rely on Instructions for Use?
Q. Yes, the percentage of doctors, you know, who rely or do not rely on the Instructions for Use? And the reason I'm asking is you were involved in the Lewis case, you know Dr. Boreham said, "I don't rely on the IFU," right?
MR. CARTMELL: Object to the form.
BY THE WITNESS:
A. If I recall, that's what she testified to.
BY MR. SNELL:
Q. Okay. Fair enough. So that's where my question is coming from.
Have you seen actually any, you know, data, any literature that's been peer reviewed or any surveys put out by AUGS, AUA, SUFU or anybody else who you would recognize as having an authoritative voice

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in the field of female pelvic medicine who have presented that data that says, Okay, this is the percentage of surgeons doing TVT retropubic or synthetic midurethral slings who rely on IFUs?
A. I don't think that study has been done.
Q. And have you seen or are you aware of any similar studies that report on how surgeons interpret the adequacy of IFUs for stress incontinence devices?
A. I have not seen any studies like that.
MR. SNELL: Okay. That's all I have. Thank you.
EXAMINATION
BY MR. CARTMELL:
Q. I have a few follow-ups, Doctor.
You were just asked about your opinion that's in your report related to tensioning of the device.
Do you recall that?
A. Yes.
Q. Now, your opinion in this case, and it's in your report, is that the TVT retropubic at issue in this case is defective, correct?
MR. SNELL: Objection; leading.
BY THE WITNESS:

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A. That is correct.
BY MR. CARTMELL:
Q. Do you have an opinion that the benefits are outweighed by the risks?
MR. SNELL: Same objection.
BY THE WITNESS:
A. That is correct.
BY MR. CARTMELL:
Q. So are you planning to offer an opinion that you could rewrite the IFU in a way that would make the product not defective?
A. One of the ways to rewrite the IFU today -- oh, specifically about --
MR. SNELL: Don't interrupt him. He is answering your question. I want to hear this answer. Go ahead.
BY THE WITNESS:
A. One of the ways to make the IFU not defective is by adding all of the risks, known risks and adverse events that are associated with the TVT device that I have outlined in my report, including frequency, severity, treatability and longevity of complications.
BY MR. CARTMELL:

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Q. Okay. But my question is, are you offering --
MR. SNELL: I'm going to object that that's not responsive to Tom's question.
BY MR. CARTMELL:
Q. Are you offering an opinion that you could rewrite the IFU with respect to tensioning and make the product not defective?
A. No.
Q. Okay. All right.
You were asked about whether or not in a particular woman you could offer an opinion about whether or not degradation caused an erosion or complication.
Do you remember that?
A. Yes. I thought it was a particular woman in a study, not a particular woman that I'm seeing in my office.
Q. You have offered testimony in the past, and is your testimony in this case that in a particular woman you can, in fact, make a determination or offer an opinion regarding whether or not degradation is leading to complications?
MR. SNELL: Objection; leading.

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BY THE WITNESS:
A. Yes, you can feel that the mesh is firm, hard, brittle. You can look at it and see flaking and fragmentation, and it can be examined under the microscope to see cracking and fragmentation.
BY MR. CARTMELL:
Q. You were asked whether or not there were any prospective studies that actually have looked at whether or not mesh in a sling is degrading and causing erosions, I think, is that right?
A. Yes.
Q. Okay. And I think you did talk about the Wang study, is that right?
MR. SNELL: Objection; leading.
BY THE WITNESS:
A. That is correct.
BY MR. CARTMELL:
Q. Now, and I think you said that maybe there are no other prospective studies that discuss that.
What is your understanding of why is that that you don't believe a randomized controlled prospective study to look at whether or not mesh is degrading and causing erosions has been done?
MR. SNELL: Objection; leading, lacks

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foundation. Go ahead.
BY THE WITNESS:
A. Well, that would necessitate taking mesh out of asymptomatic women and that would be a very difficult study to do. It would be questionable, ethical about operating on someone that is asymptomatic, to take a piece of their sling out who are not having complications from it.
But there is a wealth of studies that have looked at women that have complications, looked at their mesh under the microscope and have seen degradation that has caused the complications that they now have.
BY MR. CARTMELL:
Q. So are there a wealth, as you say, of studies that have looked at actual mesh that has been removed from women's bodies to see if, in fact, the mesh is degrading?
A. That is correct.
Q. And you've identified all of those in your report, correct?
A. That is correct.
Q. Or in the reliance list?
A. On my reliance list, yes.

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Q. And those are prospective in nature, is that right?
MR. SNELL: Objection; leading, misstates.
BY MR. CARTMELL:
Q. Or excuse me.
MR. SNELL: Misstates as well.
MR. CARTMELL: I misstated that.
BY MR. CARTMELL:
Q. Those are retrospective, is that correct?
A. That is correct.
Q. And, in fact, are there multiple studies now and papers that have discussed that in women who have pain, including dyspareunia or erosions, doctors have then and pathologists have then removed the mesh to determine whether or not there is degradation of the mesh?
A. Yes.
MR. SNELL: Form, leading.
BY MR. CARTMELL:
Q. And are there studies that you have cited to in your report and that you have referred to on your reliance list that actually have looked at and found that women who are having pain and erosions have a high rate of mesh that has degraded and

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deformed, roped, curled, folded mesh, those types of things?
MR. SNELL: Objection; form, and leading. Go ahead.
BY THE WITNESS:
A. Yes.
BY MR. CARTMELL:
Q. And are those papers papers that you rely on and that you were not asked about today but they are in your report and on your reliance list?
A. Yes, that's correct.
MR. SNELL: Same objections.
BY MR. CARTMELL:
Q. You said when you were asked about whether there is a specific prospective study in women who were receiving mesh slings that have found cytotoxicity was causing erosions, you said, erosions are -- what did you say?
A. Well, erosion is evidence of cell death which is cytotoxicity.
Q. Why did you say that in response to the question by --
A. Well, that is objective --
MR. SNELL: Form. Go ahead.

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BY THE WITNESS:
A. -- evidence that cytotoxicity took place, that the cells around either the vagina or the urethra were killed by the cytotoxic event so that now the mesh is either exposed in the vagina, in the bladder or in the urethra.
BY MR. CARTMELL:
Q. So are there prospective studies in women who have had slings, mesh slings inserted that show evidence of cytotoxicity?
MR. SNELL: Form.
BY THE WITNESS:
A. Yes. Every study that talks about mesh erosion either into the vagina, urethra or bladder is documenting cytotoxicity.
BY MR. CARTMELL:
Q. So why then when you were asked whether or not there are prospective studies that have discussed cytotoxicity in women who have had slings and whether they cause erosions, why did you say no?
A. Well, they do not use the word "cytotoxicity".
MR. CARTMELL: Okay. Thank you. That's all I have.

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FURTHER EXAMINATION
BY MR. SNELL:
Q. You just said that every study where mesh exposure is reported documents cytotoxicity, is that correct?
A. Yes.
Q. And what's your methodology for the statement that every mesh exposure is due to cytotoxicity?
A. I will --
Q. Because that's a misstatement?
A. I will clarify my answer or amend my answer.
After the vaginal wall has healed, any mesh exposure is evidence that cell death has occurred which is cytotoxicity.
Q. Okay. And which of those studies report that there was actual necrotic tissue?
A. That was not associated with a pathology report?
Q. Right.
A. If they didn't report a pathology report, then they more likely than not would not have reported necrosis. Now, the necrosis could have already

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happened and the signs of necrosis have been subsequently disappeared and all you are left with is the defect where living tissue had been before and the mesh is now exposed.
Q. In what percentage of exposures does that mechanism you just spoke to occur?
A. Well, if in all of the ones where you see an exposure, okay. Now, if you see active necrosis, then that is a cytotoxicity that is happening more contemporaneously with the exposure. Many times patients don't come in once their exposure is acutely occurring, and so you would see the old evidence of cytotoxicity, which is exposure, meaning the cells have died remote and all you are left with is the stigmata of the cell death.
Q. In what percentage of exposures that occur is active necrosis found?
A. From my clinical experience, I've seen active necrosis in a third to a half of mesh exposures.
Q. In the medical literature, what percentage of mesh exposure cases are found to be from active necrosis?
A. I -- that word "active necrosis" is not

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described in the -- in many studies.
Q. In the medical literature --
A. Now, there are retrospective reviews such as pathology studies that talk about whether there is active necrosis or if that there is signs of necrotic tissue, but we would have to pull out each individual retrospective review on mesh explants to be able to say whether by the time the pathologist got there they saw necrosis.
Q. You haven't put in your report what those pathology series showed with regard to the rate of active necrosis, correct?
A. No, I have not.
Q. All right. I believe you earlier said, too, that -- in response to Mr. Cartmell's question that there were studies that reported that women had complications and the authors found some degradation. And I think you were referring to, again, the Clave paper?
MR. CARTMELL: Objection; form.
BY THE WITNESS:
A. Could you repeat that, please?
BY MR. SNELL:
Q. Sure. Maybe I'm unclear.

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What were you referring to, what studies or data, when you told Mr. Cartmell that in women who have complications you know it's from the degradation?

MR. CARTMELL: Object to the form. It misstates the testimony.

BY THE WITNESS:

A. The studies that are on my reliance list that describe the pathological specimens. We discussed Clave, we discussed Zimmer, we discussed -- there are papers by Iakovlev and others that describe degradation associated with the review of the specimens that show degradation.

BY MR. SNELL:

Q. In none of those papers did they remove mesh from a cohort of women who didn't have any complications to see whether this cracking would be found in them too, correct?

A. That is correct, and that would be, as I responded to Mr. Cartmell's question, that would be a difficult study to perform.

Q. So this cracking could be seen out there in women who do not have complications, correct?

A. That is correct. But that doesn't mean that they are not going to have complications.

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Q. You said that you could tell if degradation -- strike that.

Did you tell Mr. Cartmell that you could -- strike that.

Did you tell Mr. Cartmell that if a woman had an exposure you could ascertain whether it was caused by degradation as compared to all of the other potential causes and patient factors and surgeon factors if you felt that the mesh was firm, hard, brittle, flaking or cracking?

A. That is degradation, yes.

Q. No. I'm asking you, in a particular woman, if you see that the mesh is firm, hard, brittle, flaking or cracking, you assumed that that exposure is because of degradation?

A. That is degradation, yes.

Q. Is the answer -- I just want to make sure I get a yes or no.

A. And that degradation was either the primary cause or one of the causes of that woman's exposure.

Q. And what methodology would allow you to say whether it was the primary or secondary cause?

A. The methodology that I am seeing a

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complication, that these complications were reported in the literature, that when you see a complication of erosion, pain, dyspareunia and the mesh is explanted that there is degradation that's going on. So with a reasonable degree of medical certainty that degradation played the primary or a contributory factor in the complication that the woman had.

Q. And in the women who in the studies reported complications yet there was no degradation or cracking seen, how do you factor that into your methodology?

A. Well, then that would be a complication that was caused by contraction, chronic foreign body reaction, chronic inflammation, roping, fraying, curling, one of those other causes which can lead to complications from a defective product.

Q. If you saw cracking and flaking, that would be -- then you would think the exposure is due to degradation?

A. That is correct.

Q. Regardless of inflammation or all of these other factors that you are out there seeing?

A. Well, there is inflammation that was going on because you have a degraded product, you are having

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an increase in chronic foreign body reaction. This is a circular process that the degradation is increasing the chronic foreign body reaction. It is increasing the surface area of the mesh that is leading to further degradation.

Q. Do any of the IFUs for stress urinary incontinence devices set forth for all of the different potential complications the frequency, severity and longevity?

A. Do?

MR. SNELL: Can you read it back, Madam Court Reporter.

(WHEREUPON, the record was read by the reporter as requested.)

BY THE WITNESS:

A. There is references to the longevity of certain complications, such as transient foreign body reaction, transient local inflammation, but specifically to the extent of telling what the frequency is of individual complications and severity of individual complications, the longevity and treatability of individual complications, those have not been described in the TVT IFUs.

MR. SNELL: Move to strike. My question went

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beyond the TVT IFU.
Can you read the question back?
MR. CARTMELL: Are you asking about other products?
MR. SNELL: Yes, for any -- you have to listen to the question.
MR. CARTMELL: You didn't say anything about other products.
MR. SNELL: Okay. Well, just -- can you read the question back?
(WHEREUPON, the record was read by the reporter as requested.)
BY THE WITNESS:
A. For the TVT, TVT-O, TVT-Secur, TVT Abbrevo, no.
BY MR. SNELL:
Q. For all of the other stress incontinence devices?
MR. CARTMELL: Other manufactures?
BY MR. SNELL:
Q. Other manufactures, do you know whether or not they state the frequency, severity --
MR. CARTMELL: If you know exactly what all of the others say, then you can answer. If you don't

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know, don't speculate.
BY THE WITNESS:
A. I will not speculate on all of the other IFUs.
BY MR. SNELL:
Q. You don't know as you sit here today, correct?
A. I know about the ones that I've described before.
Q. Can you just answer my question yes or no? I'm literally looking for an honest answer. Can you as you sit here today tell me that other manufacturers' stress incontinence IFUs report frequency, severity, treatability and longevity for complications associated with their stress incontinence devices, yes or no? That's all I want no know.
A. Each individual complication?
Q. Yes, sir.
A. The ones I have seen, no.
MR. CARTMELL: You are now going beyond the scope of my cross with questions like that which is not allowed, so I'm about to shut you down.
MR. SNELL: No, no. He went into frequency,

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severity. I'm circling back around.
MR. CARTMELL: I didn't ask him about IFUs.
BY MR. SNELL:
Q. Now, if you don't feel in a particular woman that the mesh is firm or hard or brittle, flaking or cracking, if you don't feel that or if it's not described, then one can't reliably say scientifically that her exposure was due to degradation, correct?
MR. CARTMELL: Object, misstates his prior testimony. He has talked in multiple depositions about degradation. You are getting into things we've already talked about. He has given testimony on degradation at trial and on that exact same subject of whether or not --
MR. SNELL: You've reopened all of this stuff up with your like these big, broad, sweeping questions that you do in your direct.
MR. CARTMELL: No.
BY MR. SNELL:
Q. All right. Let me make it more simple then. I'm going to focus on Mr. Cartmell's question and your answer.
In a particular woman where you don't feel

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that the mesh is firm, hard, brittle, flaking or cracking but she has an exposure, how do you determine what is the cause of that exposure?
MR. CARTMELL: Same objection. He has testified to that multiple times at other trials and other depositions about how he goes about determining what the specific cause is of an erosion. That's been gone over multiple times.
MR. SNELL: No.
MR. CARTMELL: Yes.
MR. SNELL: When has he gone over that?
MR. CARTMELL: He has gone over it at trial. You've said multiple times in depositions you can't tell whether it's the roping or the curling or the fraying or the degradation.
MR. SNELL: He answered my question and now he is changing his answer.
MR. CARTMELL: No, he is not.
MR. SNELL: Yes, he is.
MR. CARTMELL: What you are doing is you are trying to ask it multiple times to try to get a different answer.
MR. SNELL: No, I'll withdraw that question and we'll see.

BY MR. SNELL:
Q. I can rely on prior statements you've made, correct?
A. Yes, sir.
Q. Fair enough.
MR. SNELL: That's it. Let's shut it down.
(Time Noted: 6:39 p.m.)
FURTHER DEPONENT SAITH NOT.

REPORTER'S CERTIFICATE

I, JULIANA F. ZAJICEK, C.S.R. No. 84-2604, a Certified Shorthand Reporter, do hereby certify:

That previous to the commencement of the examination of the witness herein, the witness was duly sworn to testify the whole truth concerning the matters herein;

That the foregoing deposition transcript was reported stenographically by me, was thereafter reduced to typewriting under my personal direction and constitutes a true record of the testimony given and the proceedings had;

That the said deposition was taken before me at the time and place specified;

That I am not a relative or employee or attorney or counsel, nor a relative or employee of such attorney or counsel for any of the parties hereto, nor interested directly or indirectly in the outcome of this action.

IN WITNESS WHEREOF, I do hereunto set my hand on this 24th day of September, 2015.

JULIANA F. ZAJICEK, Certified Reporter

INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it. It will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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ACKNOWLEDGMENT OF DEPONENT

I,______________________, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

____
BRUCE A. ROSENZWEIG, M.D. DATE

Subscribed and sworn
to before me this
_____ day of ______________, 20____.

My commission expires:______________

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Notary Public

LAWYER'S NOTES

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